Reviving Public Trust in Science | Early Career Primer For Left Main Revascularization

OCTOBER 2021 • VOL. 50 • NUMBER 10

Cardiology

A Member Publication of the American College of Cardiology

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Registration is now open for the New York Cardiovascular Symposium, taking place virtually Dec. 11 to 12. Learn from world-renowned cardiologist, *JACC* Editor-in-Chief and Course Director **Valentin Fuster, MD, PhD, MACC,** and some of the most prestigious names in cardiology. New this year, all sessions will be live streamed in real-time!

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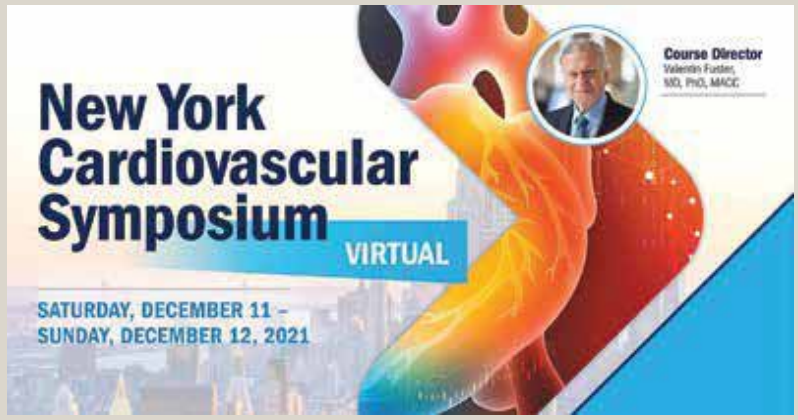
Scan the QR code for the details including credit information, the agenda and more – and register today!



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Don't miss the Quick Tips videos and review Expert Analysis and Opinion – Understanding Cardiac Amyloidosis, where **Frederick L. Ruberg, MD, FACC,** and **Mathew S. Maurer, MD, FACC,** expand on the nomenclature/epidemiology, diagnosis, symptom management, and amyloid-specific therapy of cardiac amyloidosis. Keep current with the new guidelines and learn at your own pace. Scan the QR code to access the course.

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Access it all at *ACC.org/OnlineCourses*.

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About the American College of Cardiology
The American College of Cardiology envisions a world where innovation and knowledge optimize cardiovascular care and outcomes. As the professional home for the entire cardiovascular care team, the Mission of the College and its more than 54,000 members is to transform cardiovascular care and to improve heart health. The ACC bestows credentials upon cardiovascular professionals who meet stringent qualifications and leads in the formation of health policy, standards and guidelines. The College also provides professional medical education, disseminates cardiovascular research through its world-renowned *JACC* Journals, operates national registries to measure and improve care, and offers cardiovascular accreditation to hospitals and institutions. For more, visit *ACC.org*.

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Reviving **Public Trust** in Science

Guest Editorial

Janet S. Wright, MD, FACC

I learned about trust in science around the dinner table, on the hallway phone, and in the driveway. My dad was a family practitioner, the only doctor for several counties in rural Arkansas. During my childhood, a time before answering services, pagers or cell phones, when people needed "Doc," they just called our house. My mother used to say with gentle resignation that when we sat down for supper, a light flashed atop the water tower, signaling the perfect time to call.

I saw first-hand what data continue to show us today: that nurses, like my mom, are among the most trusted individuals on the planet. Many people calling our house wanted to "vet" their symptoms with "Miz Doc" before speaking with dad. If someone had an urgent need – cotton gin accident, gunshot or a baby crowning – they just screeched into the driveway and honked until my dad or mom appeared. Along with fear, shock and urgency, the faces I saw were also filled with trust.

My experiences with trust have been many since those days. In my inaugural attempt as a medical student to take a patient's history, I dreaded asking what seemed to be very personal questions. But instead of taking offense, the person I was interviewing invariably answered frankly and in detail. The words "sacred trust" popped to mind and have stayed with me ever since. I tried to honor that trust during my years of practice in Northern California, years that were enriched and informed by ACC colleagues and the opportunities for service and learning that the College provided me.

As a member, trustee and staff, I saw how trust operates within ACC, from the processes that protect the scientific integrity of documents and manuscripts to the interactions among members on committees and task forces to the relationships with partners, including other societies, government and industry.

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One of the ways to build trust is to be trustworthy, to tell the truth. In this regard, I applaud the College's work to advance diversity, inclusion and equity and to speak to the impact of racism, discrimination, and other powerful determinants of health and well-being. These actions create opportunities to build and strengthen trust, repair past damage and prevent future harm.

For the first eight years of my decade at the Centers for Disease Control and Prevention (CDC), I served as executive director of Million Hearts®, a public-private initiative co-led with the Centers for Medicare and Medicaid Services to prevent heart attacks, strokes and other cardiovascular events. New in federal service, I was swept away by the dedication, scientific rigor and expertise manifested by the Million Hearts® team. They spent more than two years prior to the launch in 2011 poring over the evidence, analyzing data, prioritizing interventions and crystallizing the "case" for implementing what works to prevent cardiovascular disease. Their diligence led to hearty acceptance of the framework and widespread participation – evidence of trust – among federal and private sector partners, including ACC.

In 2020, the world changed. SARS-CoV-2 was novel, and that made everyone on earth depend on science. Science was central to the global response and was perhaps never before so tested, twisted and triumphant.

Although vaccine skepticism, misinformation, and tensions between science and policy were not new in 2020, the pandemic's devastation fertilized these issues and transformed the trust landscape. During my two-year service in the Office of the Surgeon General, I worked with gifted and dedicated public servants, committed to addressing the inequities made manifest by COVID-19, translating the rapidly evolving science for a frightened public, and balancing the urgency of the COVID-19 response with the imperative to get the science "right." These individuals operated in a highly polarized environment equipped with the echo chamber that is social media. They engaged a public that often perceived shifts in guidance as evidence of mistakes, rather than the iterative, messy, evolution of thought that is science. While trust in clinical teams has remained high, trust in science institutions has suffered.

Although vaccine skepticism, misinformation, and tensions between science and policy were not new in 2020, the pandemic's devastation fertilized these issues and transformed the trust landscape.

Going forward, it is time for all of us – clinicians, public health professionals, researchers and patient advocates – to strengthen the public's trust in science. In this mission, I know that CDC and ACC are aligned. Together, we can commit to continuing to provide clarity about what we know and what we don't know; maintaining scientific integrity in our publications, presentations and policies; and speaking the truth and igniting action to address the drivers of cardiovascular health inequities. As we heal from COVID-19, we can and must revive the public's trust, the same trust that was present decades ago in rural Arkansas.

Wright is director of the Division for Heart Disease and Stroke Prevention at the Centers for Disease Control and Prevention

Members on the **Move**

Richard Kovacs Named ACC Chief Medical Adviser/Chief Medical Officer

Richard "Dick" Kovacs, MD, MACC, will assume the role of ACC Chief Medical Adviser/Chief Medical Officer beginning next month. As CMA/CMO he will work with physician leadership and staff to provide clinical advice in fulfilling the College's mission of transforming cardiovascular care and improving heart health.

"Dick has been an exemplary leader in the College throughout his tenure as an ACC member, leading not only at the highest roles, but also in various committees and task forces ranging from finance to science and quality," says ACC CEO **Cathleen C. Gates.** "His history of leadership in medicine and his breadth of experience throughout the different areas of the College make him a perfect fit to serve as CMA/CMO and bring his clinical expertise and knowledge to the ACC staff."

In his role as CMA/CMO, Kovacs will counsel ACC staff on emerging clinical issues and help assess complex medical and scientific data. As a member of the senior executive staff, he will also work closely with partner cardiovascular societies, medical specialty organizations and external collaborators, including regulatory and governmental agencies, payers, and credentialing and licensing organizations.

"I've devoted a large portion of my professional career to volunteer member service to the ACC to help advance the mission and propel the field of cardiology forward," says Kovacs. "I'm honored to expand my involvement as ACC chief medical adviser and chief medical officer and more closely work with the College staff and physician leaders to transform cardiovascular care on a global scale."

Scan the QR code to read more about Kovacs and the CMA/CMO role.

Katie Berlacher Named Next Annual Scientific Session Vice Chair

Katie Berlacher, MD, MS, FACC, will be the next vice chair of the ACC's Annual Scientific Session, starting with ACC.23 and ACC.24. She will transition to chair for ACC.25 and ACC.26.

"The College has an awesome opportunity to lead global cardiovascular education, impacting care delivery, population health, scientific discovery – and so much more," Berlacher says. "I am both thrilled and humbled by the appointment as vice chair and am looking forward to working with the team as we build annual sessions that are grounded in science, inspired by innovation and focused on equity."

The Annual Scientific Session vice chair and chair are responsible for leading the development of ACC's flagship annual meeting. ACC.22 will be held April 2-4, 2022, in Washington, DC, and led by current Annual Scientific Session Chair **Pamela Morris, MD, FACC,** and Vice Chair **Douglas Drachman, MD, FACC.**

Scan the QR code to read more about Berlacher and her role.

Megan Coylewright Named Editor of CardioSmart

Megan Coylewright, MD, MPH, FACC, has been named editor of ACC's CardioSmart patient engagement initiative. As editor, Coylewright will serve a three-year term and be responsible for advising and ensuring clinical accuracy of the editorial content development on *CardioSmart.org,* as well as assist in developing innovative strategies to help the ACC best engage, educate and activate the diversity of cardiovascular patients in their care.

"The role of editor of CardioSmart is an ideal blend of my daily clinical work performing transcatheter valve repair and replacement, research in shared decision-making, and our community and nationally-based efforts to ensure we are using best practices in promoting diversity, inclusion and belonging in all that we do," Coylewright says. "I am thrilled to work with the talented staff of CardioSmart. Together, we will partner with patients and the cardiovascular care team to further embed the patient voice in our daily practices, scholarship, guidelines and clinical trials."

Scan the QR code to read more about Coylewright and her role.

Start Your Saturdays With **Coffee With the ACC President**

The monthly Coffee With the ACC President series hosted by **Dipti Itchhaporia, MD, FACC,** continues to provide ACC members with unique opportunities to discuss important topics facing clinicians and patients with diverse thought leaders ranging from cardiovascular experts to members of Congress to former Olympians and more.

Tune in on Saturday, Nov. 13 at 10 a.m. ET for the next Coffee with Itchhaporia and featured guests **Vincent Covello, PhD,** director of the Center for Risk Communication, and **Randy Hyer, MD, PhD, MPH,** senior vice president of Global Medical Affairs at Moderna. Visit *ACC.org/ACCCoffeeTable* to save your spot.

Scan the QR code to access past Coffees, including a conversation on health policy and advocacy with Sen. **Bill Cassidy, MD,** from Louisiana, and a robust discussion on teambuilding and leadership with Olympic gold medalist **Maddie Musselman** and veteran US Navy SEAL and author **Chris Fussell.**

Recognizing Hospital Commitments to **Quality Improvement**

The 2022 *U.S. News & World Report* "Best Hospitals" guidebook, recognizes the more than 2,000 hospitals and facilities participating in NCDR registries or those that have earned an accreditation or certification from ACC Accreditation Services.

As the global professional organization for the entire cardiovascular care team, the ACC is committed to supporting patients, caregivers and health care professionals by ensuring the highest-quality care is delivered to every patient, every time. Patients and caregivers can trust that the hospitals, health systems and centers participating in NCDR and ACC Accreditation Services, as well as those that have received the Chest Pain – MI Registry Performance Achievement Award or the HeartCARE Center designation, are committed to delivering the best cardiovascular care and are dedicated to quality outcomes and process improvement.

View the full list of institutions participating in NCDR and ACC Accreditation Services at *ACC.org/USNWR*.

Gearing Up For **AHA** and **TCT** 2021

The ACC will be providing coverage of late-breaking science and featured research, along with other meeting highlights, from TCT 2021 and AHA 2021, respectively.

TCT 2021 kicks off first from Nov. 4 to 6 in Orlando, FL, and is being broadcasted live. Don't miss a Late-Breaking Clinical Trials Session in collaboration with *JACC* on Nov. 6; a Hot Topic session with leaders from ACC, AHA and ESC looking beyond guidelines at controversies in the management of valvular heart disease on Nov. 4; another Hot Topic session featuring ACC President **Dipti Itchhaporia, MD, FACC,** and others addressing revascularization decisions in chronic coronary syndromes; and more. Scan the QR code for the program guide.

AHA Scientific Sessions 2021 will take place Nov. 13 to 15 as an all-virtual experience. Among the highlights, look for an AHA/ACC Joint Session on advancing cardiovascular health equity; focused guideline sessions exploring valvular heart disease and heart failure, respectively; and more. Scan the QR code for more program information.

Look for coverage of *JACC* Journals simultaneous publications, trial summaries, news stories, video wrap-ups and more on *ACC.org* starting the day before each meeting. Also check your email for special ACC Update newsletters featuring daily highlights from each meeting and stay up to date in real time by following @ACCinTouch on Twitter. Bookmark *ACC.org/TCT2021* and *ACC.org/AHA2021* for all the coverage from the *ACC.org* Editorial Team.

In Memoriam: **Attilio Maseri, MD, FACC**

Internationally renowned Italian cardiologist **Attilio Maseri, MD, FACC,** passed away at the age of 85. Maseri, who served as cardiologist to Queen Elizabeth II and Pope John Paul II, is best known for his original research related to ischemic heart disease. During his illustrious career that spanned Italy and the UK, he published more than 750 articles and medical texts and received numerous awards and honors, including the Gold Medal for Meritorious Science and Culture and the title of Knight of the Grand Cross of Merit of the Italian Republic in 2005.

The ACC's Maseri-Florio International Lecture at the College's Annual Scientific Session was established by a grant from Maseri and his wife and has featured many distinguished global cardiovascular clinicians since its creation in 2002.

IMMUNIZATION
AN IMPORTANT SHOT AT PREVENTION

5

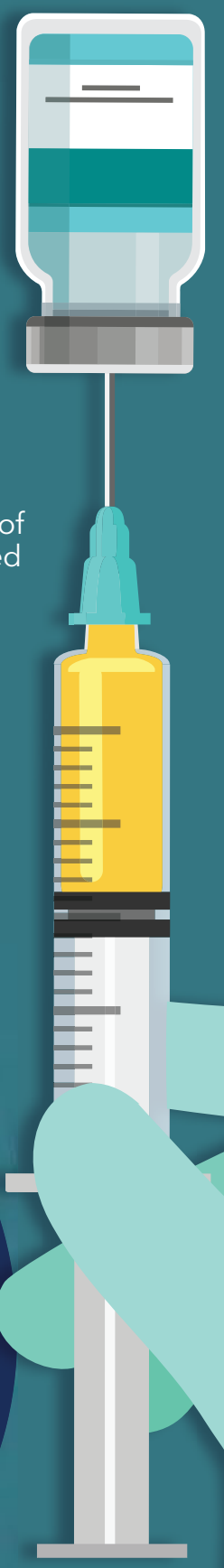
The number of miles within which most Americans live from a pharmacy, allowing ready access to trusted pharmacists who have direct knowledge of their patient populations and who are trained to counsel patients and provide vaccine education along with administering vaccines.

36%

The percent reduction in the risk for major adverse cardiovascular events in patients with heart disease from getting the annual flu shot. In persons with heart failure, the risk of death is 50% lower with a flu shot.

49%

The proportion of people vaccinated in the first two weeks of September through the retail pharmacy program who were from a racial or ethnic minority group.



60%

The proportion of cardiologists who frequently discuss the need to get a flu vaccine with their patients.

133 million

The number of COVID-19 vaccines administered and reported by retail pharmacies across programs in the U.S., as of Sept. 22.

Source: CDC: *www.cdc.gov/vaccines/covid-19/retail-pharmacy-program/index.html*

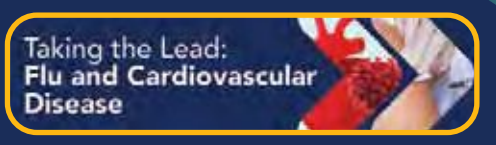
10x

The increased risk of a heart attack in a person with heart disease within three days of getting the flu.

7 The number of specialty societies, including the **ACC**, collaborating with the U.S. Centers for Disease Control and Prevention and the Council of Medical Specialty Societies to implement targeted quality improvement strategies and activities to increase immunization rates in high-risk adults. "Cardiovascular disease patients are at higher risk of complications from many viruses for which there are safe and effective vaccines," says ACC CEO **Cathleen C. Gates.** "Together with our fellow health care societies we are eager to help educate the most at-risk patients and increase access to life-saving vaccines." Scan the QR code to learn more.

Celebrating American Pharmacists Month

The ACC recognizes the contributions of pharmacists to the health care of patients every day and especially during the COVID-19 pandemic. Thank you to our pharmacist colleagues for their work within the ACC to transform cardiovascular care and improve heart health.



The annual flu shot has measurable benefits for patients with cardiovascular disease

ACC's new online course **Taking the Lead: Flu and Cardiovascular Disease** provides actionable knowledge to help make influenza vaccination an integral part of heart disease management. Gain insights on the connection between influenza and cardiovascular outcomes and the role of the CV Care Team. The free self-paced course includes challenging case scenarios, self-assessment, expert debate and infographics. Scan the QR code to get started.

CardioSmart
American College of Cardiology

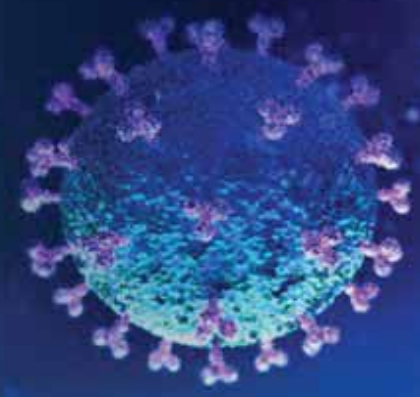
Patient Resources From CardioSmart

Scan the QR code for tools and resources for your patients, including infographics on the value of flu shots.

Scan the QR code for patient information on the COVID-19 vaccine.

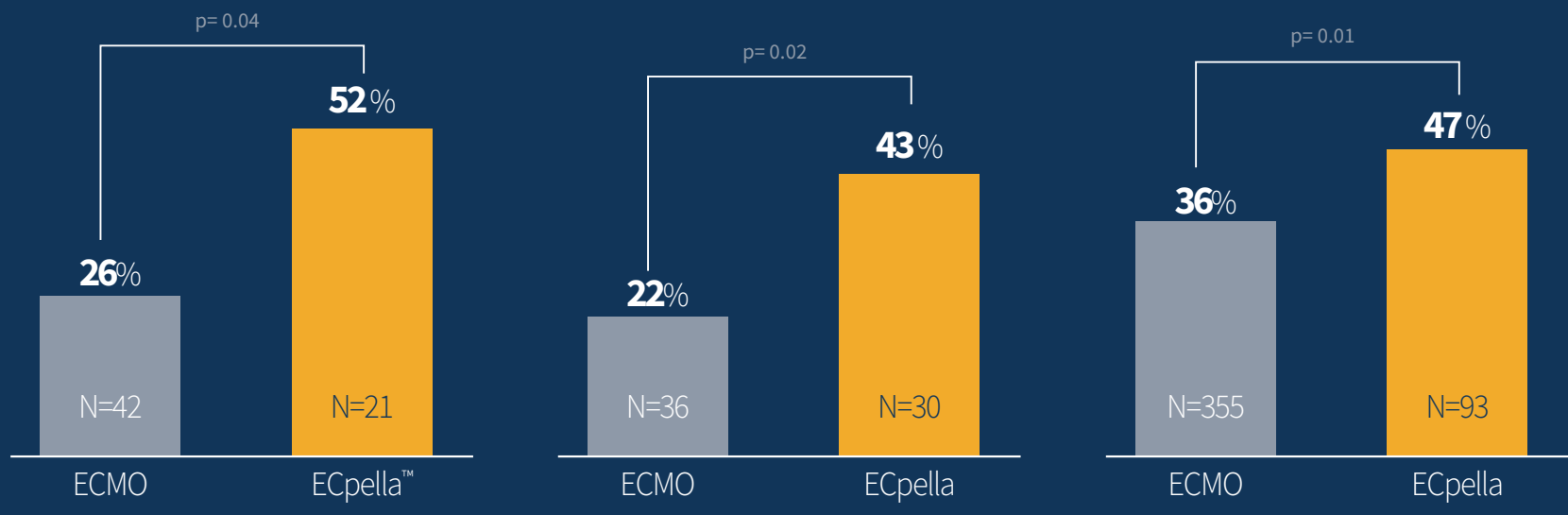
Impella®
Advancing the way heart failure is treated

Unloading Therapy for **COVID-19 Patients**



The FDA has issued an emergency use authorization (EUA) for Impella® heart pumps to provide left ventricular unloading and support for COVID-19 patients who are undergoing ECMO treatment and develop pulmonary edema or myocarditis.

Impella Unloading in ECMO Treated Patients in Cardiogenic Shock is Associated With Improved Survival in Several Published Multi-Center Reports



Pappalardo F, et al., Eur J Heart Fail 2016

Patel S, et al., ASAIO J 2018

Grajeda Silvestri E, et al.,J of Cardiac Surgery 2020

To learn more visit, **www.HeartRecovery.com**

SCAN ME

* ECpella = ECMO + Impella

Emergency Use Authorization

Impella Left Ventricular (LV) Support Systems (Impella 2.5®, Impella CP®, Impella CP® with SmartAssist®, Impella 5.0®, and Impella 5.5® with SmartAssist®) are authorized for emergency use by HCPs in the hospital setting for providing temporary (≤ 4 days for Impella 2.5, Impella CP, and Impella CP with SmartAssist; and ≤ 14 days for Impella 5.0 and Impella 5.5 with SmartAssist) LV unloading and support to treat critical care patients (i.e. patients in the intensive care unit) with confirmed COVID-19 infection who are undergoing ECMO treatment and who develop pulmonary edema while on V-A ECMO support or late cardiac decompensation from myocarditis while on V-V ECMO support. The Impella LV Support Systems have neither been cleared or approved for the authorized indication for use. The Impella LV Support Systems have been authorized for the above emergency use by the FDA under an EUA. The Impella LV Support Systems have been authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of medical devices under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

All cardiovascular procedures have risk. Potential adverse events associated with the use of Impella include: acute renal dysfunction, aortic valve injury, bleeding, cardiogenic shock, stroke, hemolysis, limb ischemia, myocardial infarction, renal failure, thrombocytopenia, vascular injury and death.

To learn more about the Impella platform of heart pumps, including important risk and safety information associated with the use of the devices, please visit: ***www.abiomed.com/important-safety-information***

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JACC Review Offers **Closer Look at Sports and Exercise** Cardiology and Approaches to Care

Members of the ACC Sports and Exercise Cardiology Section Leadership Council offer a closer look at common exercise-induced cardiovascular adaptations and review the importance of a shared decision-making approach to caring for athletes, in a new state-of-the-art review paper published in the *Journal of the American College of Cardiology*.

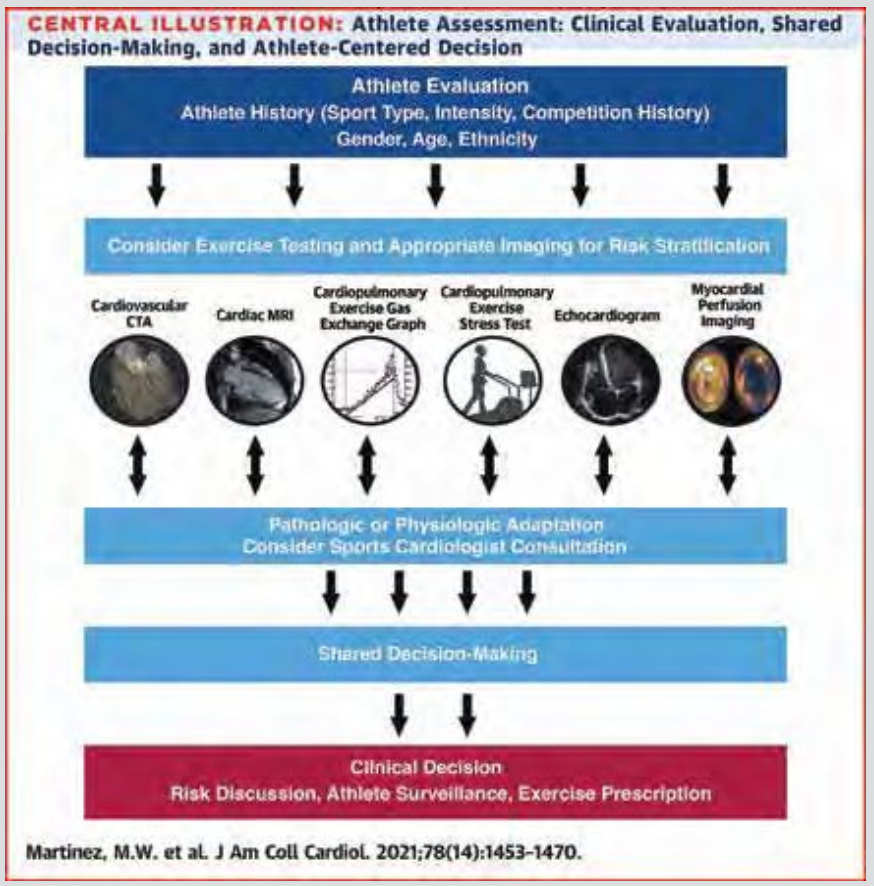
With the role of the sports cardiologist having evolved "into an essential component of the medical care of athletes," **Matthew W. Martinez, MD, FACC; Jonathan H. Kim, MD, MSc, FACC,** and colleagues review the effects of exercise on the "athlete's heart" and dive into specific clinical scenarios germane to sports cardiology.

Among the specific highlights, the authors note that athletes "may develop physiological adaptations found on ECG and imaging that may overlap with pathological conditions." They also stress that "ECG and imaging findings must be integrated with both the clinical history and other diagnostic testing to determine expected adaptions vs. pathological abnormality." For those athletes with asymptomatic and symptomatic cardiovascular disease, the paper urges risk stratification be considered before return to competitive sports play.

Patient-centered shared decision-making is also a focal point of the paper, with the authors noting such an approach "has become the accepted paradigm of treatment option discussions with patients." According to Martinez, et al., the five pillars of knowledge, humility, respect, teamwork and communication should be used by providers in discussions with the patients. With the ultimate goal of reaching a clinical decision that is then followed up by ongoing risk discussions, athlete surveillance and exercise prescription.

"[Shared decision-making] should not be a 'rubber-stamp' allowance to continue with sports participation for all athletes," write Martinez, et al. "Risk stratification of the athlete with consultation by experts in sports cardiology and other disciplines is mandatory. Along with the risk of sudden cardiac death, the focus of [shared decision-making] must include the potential negative psychological, social, and overall health impacts of sports restriction."

Martinez MW, Kim JH, Shah AB, et al. *J Am Coll Cardiol* 2021;78:1453-70.



Review Explores **Obesity Management and CV Implications**

Obesity is a heterogeneous condition and the prevalence is increasing globally, according to a review published in the *Journal of the American College of Cardiology*. As part of managing obesity, attention should be given to two main subgroups: overweight or moderately obese patients with an excess of visceral adipose tissue (VAT) and severely obese patients.

Jean-Pierre Després, CQ, PhD, et al., review population-based solutions and clinical approaches for obesity management and assess the challenges presented by today's economy and obesogenic environment. According to the authors, obesity is connected to type 2 diabetes and cardiovascular disease and this association could reduce life expectancy.

"Among overweight and moderately obese patients, excess VAT accumulation and deposition of fat in undesired sites are key drivers of unfavorable health outcomes, irrespective of the patient's body weight," the authors explain. "Severe obesity must also be recognized because it is associated with important health issues, and dealing with this high-risk obesity phenotype is required in terms of health risk and clinical management."

The review also highlights that health risks can be determined by analyzing individual variations in regional body fat distributions, and that patients with excess visceral fat often contain additional fat in the heart, kidneys, liver, pancreas and skeletal muscle. In addition, elevated waist circumference should be routinely monitored due to its association with health hazards. Further, even without weight loss, interventions that target waist circumference reduction benefit patients at cardiovascular risk.

Després et al., conclude that moving forward, "cardiologists must play an important leadership role in recommending the development of multidisciplinary clinical teams … as well as the implementation of the public health policies required to have a long-term impact on the socioeconomic causes of obesity."

Després JP, Carpentier AC, Tchernof AT, et al. *J Am Coll Cardiol* 2021;78:513-31.

What Are the Causes of Death After Type 2 MI and Myocardial Injury?

After type 2 myocardial infarction (T2MI) and myocardial injury, cardiovascular death was often linked to heart failure, stroke and vascular disease, according to a study published in the *Journal of the American College of Cardiology*.

In a community cohort study, **Claire E. Raphael, MBBS, PhD,** et al., assessed the cause-specific mortality rate in 4,665 patients after T2MI and myocardial injury compared to type 1 myocardial infarction (T1MI). Each patient selected had a serum cardiac troponin T (cTnT) concentration above the 99th percentile upper reference limit (≥0.01 ng/mL) reported in hospitals or clinics in Olmsted County, MN, from Jan. 1, 2003, to Dec. 31, 2012.

The cohort excluded patients with a history of MI, and mortality causes were categorized as either cardiovascular or noncardiovascular, with cardiovascular deaths including acute MI, heart failure, cardiac death, vascular death and stroke.

The researchers identified 1,022 T2MI patients, 1,345 T1MI patients, 2,282 myocardial injury patients, and only 16 patients with other MI. After T2MI and myocardial injury, cardiovascular death was most frequently caused by heart failure, stroke or vascular disease. Compared to T1MI, fatal acute MI rates were lower after T2MI and myocardial injury.

"There remains a need to establish targets for cardiovascular mortality risk reduction after both T2MI and myocardial injury," the authors conclude. "The lower risk of fatal MI in the current study together with the low risk of nonfatal MI after T2MI that we previously demonstrated suggest that routine secondary preventative therapy may be less impactful than in T1MI." They add that moving forward, "further work is needed, including studies using a high-sensitivity troponin assay."

Raphael CE, Roger VL, Sandoval Y, et al. ***J Am Coll Cardiol*** 2021;78:4156.

Study Explores **Gender Disparities in Cardiac EP Training** in the US and Canada

In pursuit of a career in clinical cardiac electrophysiology (EP), women are more likely to withdraw than their male colleagues due to radiation concerns, interest in another field, lack of female role models, a perceived "old boys' club" culture, and concerns about discrimination and harassment, according to results of an ACC survey published in the *Journal of the American College of Cardiology*. Adequately addressing these factors could help close the gender gap in the EP field.

Nashwa Abdulsalam, MBBCh, et al., developed and distributed an ACC online survey to 933 Fellows in Training (FITs) in the U.S. and Canada. The multiple-choice survey sought to identify the factors that persuade or dissuade FITs toward cardiovascular subspecialties, particularly EP, and assess how these factors differ by gender.

The results showed that out of the 933 FITs who participated in the survey, 129 wanted to specialize in EP, 259 wanted to specialize in interventional cardiology, and 545 were either undecided or sought a different field altogether. Gender played a significant role, with 84% of male FITs pursuing EP compared to only 16% of female FITs. Female FITs were most influenced by the presence of a female role model in the field vs. men.

"Women pursuing careers in cardiology continue to face many unique challenges including discrimination, limited number of strong mentors and female leaders, impediments to career advancement and work-life balance issues, which have not changed substantially over the last two decades," the authors conclude. "A greater commitment among leaders of internal medicine and cardiovascular training programs and professional organizations is necessary to improve gender diversity in the field of clinical cardiac electrophysiology."

In a related editorial comment, **Erin D. Michos, MD, MHS, FACC,** et al., add that "Representation really matters, and the current survey findings reaffirmed this importance. Mentorship and female role models were some of the most influential factors in choosing EP. Women EP cardiologists need to be visible to the pipeline, the early learners such as undergraduate students, medical students, and internal medicine residents."

Abdulsalam N, Gillis AM, Rzeszut AK, et al. *J Am Coll Cardiol* 2021;78:898-909.

What is the Safety, Efficacy of Metoprolol Therapy in **Critically Ill COVID-19 Patients?**

Intravenous metoprolol therapy may safely reduce lung inflammation and improve oxygenation for COVID-19 patients with acute respiratory distress syndrome (ARDS), according to results of the MADRID-COVID pilot trial published in the *Journal of the American College of Cardiology*.

Agustín Clemente-Moragón, BSc, et al., assessed the effects of intravenous metoprolol therapy on respiratory function and alveolar inflammation in 20 COVID-19 patients with ARDS using electrocardiogram monitoring and echocardiography. Each patient was on invasive mechanical ventilation and randomized to either 15 mg metoprolol daily or control treatment. Before and after their treatment, each patient had bronchoalveolar lavage (BAL).

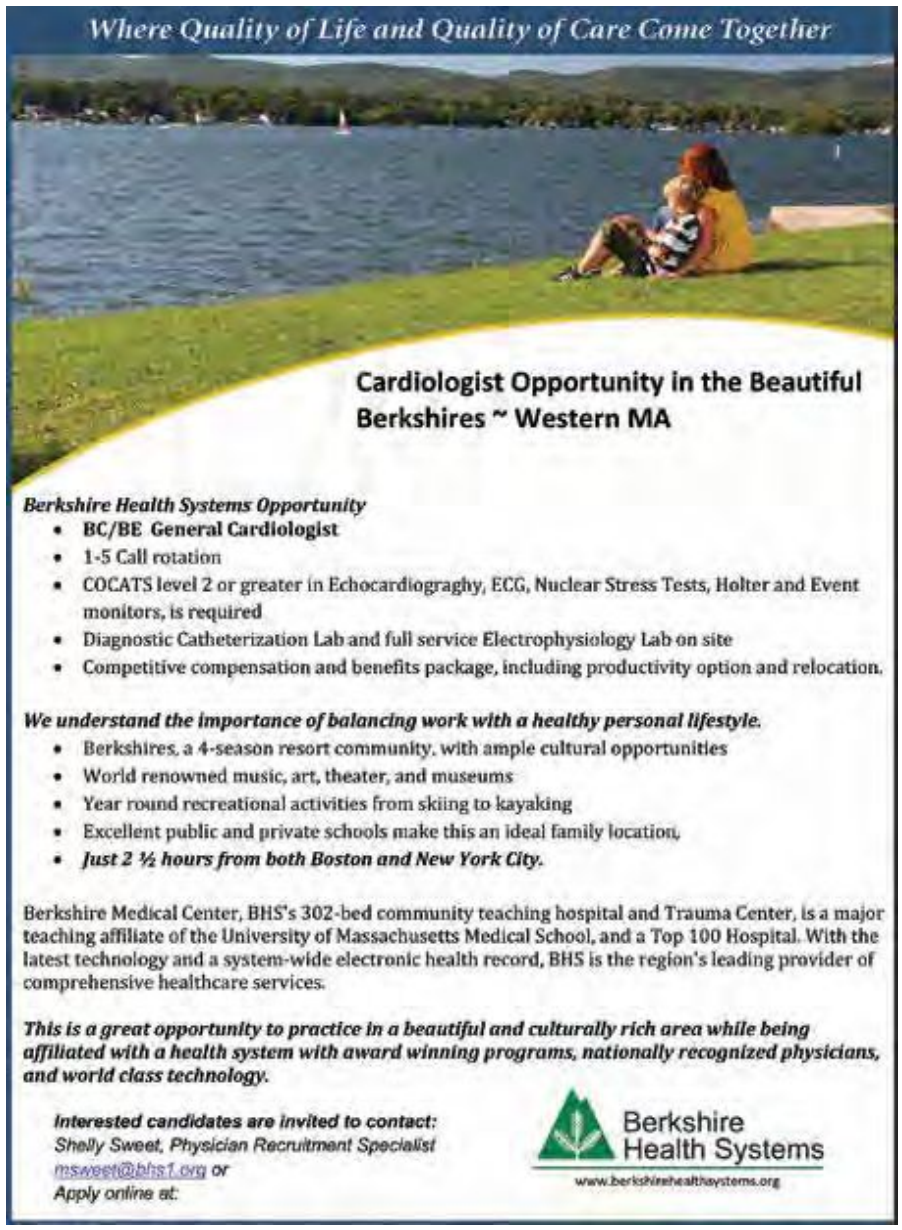
The results showed that metoprolol therapy produced no side effects, and there were no variations at baseline in the neutrophil content in BAL between the two groups. On day four, patients who received metoprolol therapy displayed noticeably fewer neutrophils in BAL than those in the control group. Metoprolol therapy reduced markers of lung inflammation, such as neutrophil extracellular traps content. It also noticeably improved oxygenation after three days of treatment. These variables were unaffected in the control group.

"Future studies with larger sample sizes are needed to confirm the benefit of metoprolol in critically ill patients with COVID-19 and potentially other inflammatory etiologies of acute respiratory distress syndrome," the authors conclude.

In a related editorial comment, **Mourad H. Senussi, MD, MS,** states that "this study uses a readily available, safe, and inexpensive medication, has a simple study design and most importantly shows biological plausibility. Although observed in COVID-19 patients, this sets the groundwork for further research in the use of beta blockade in the critically ill. Further studies are needed to elucidate and identify where along the inflammatory spectrum these critically ill patients lie, which patients would benefit from [beta]-blockers and at what time point during their hospital stay."

"This is a preliminary study looking at mechanisms of potential benefit but requires far more study," adds **Kim A. Eagle, MD, MACC,** editor in chief of ACC.org.

Clemente-Moragón A, Martínez-Milla J, Oliver E, et al. *J Am Coll Cardiol* 2021;78:1001-11



Rescue-Breathing CPR Preferred Method For Pediatric OHCA

While compression-only cardiopulmonary resuscitation (CO-CPR) was the most common type of bystander CPR in pediatric out-of-hospital cardiac arrest (OHCA), cardiopulmonary resuscitation with rescue breathing (RB-CPR) should continue to be the preferred CPR method for pediatric OHCA, according to a study published in the *Journal of the American College of Cardiology*.

Maryam Y. Naim, MD, MSCE, et al., compared the survival rate in RB-CPR and CO-CPR after nontraumatic pediatric OHCA in patients ≤18 years old between 2013 and 2019 in the Cardiac Arrest Registry to Enhance Survival database. The participants were split into age groups: infants less than one year of age, children between one and 11 years old, and adolescents 12 to 18 years old. The primary outcome was neurologically favorable survival at hospital discharge.

The results showed that 46.5% of the 13,060 pediatric OHCAs received bystander CPR, with CO-CPR classified as the most common CPR type. RB-CPR and CO-CPR independently had better neurological outcomes compared with no CPR performed at all. However, compared with CO-CPR, RB-CPR was associated with higher odds of favorable neurological outcomes for infants, children and adolescents. The analysis found RB-CPR was also associated with higher odds of overall survival compared with CO-CPR.

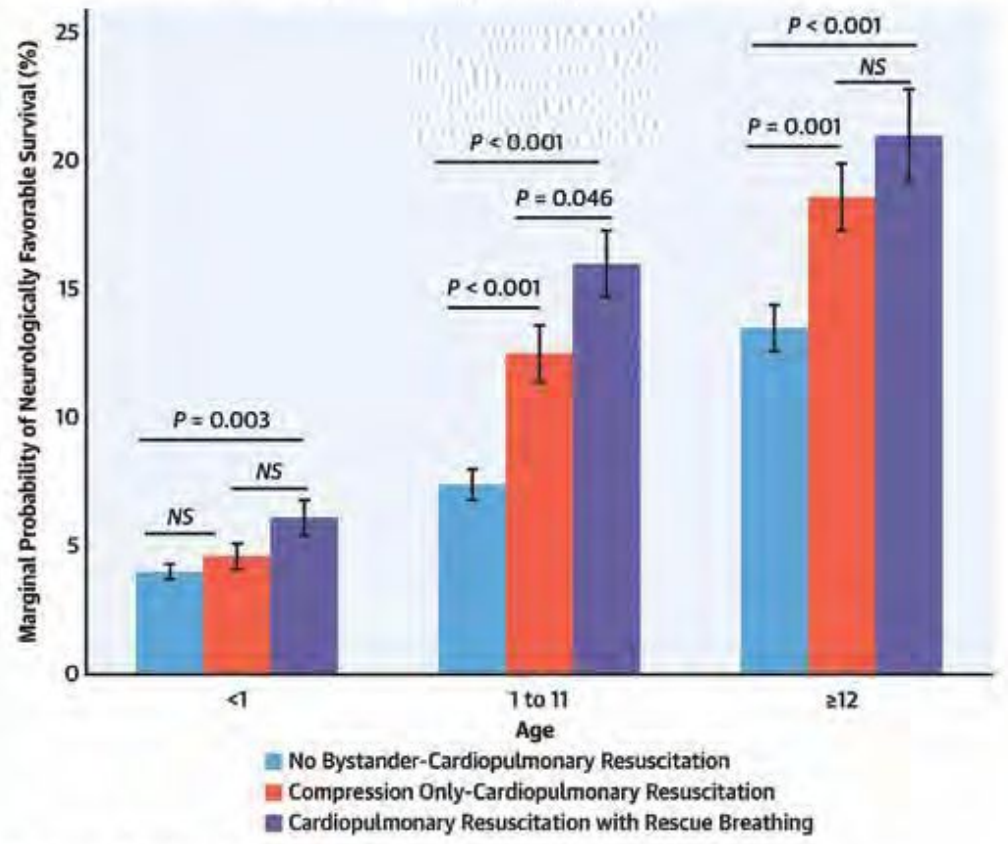
Compared with children and adolescents, infants were found to have different outcomes when it came to CO-CPR and RB-CPR. The researchers found RB-CPR resulted in better outcomes than CO-CPR for all pediatric age groups. However, the researchers also found performing CO-CPR was better than no CPR in children and adolescents, but not infants; neurologically favorable survival in infants was only observed with RB-CPR. The researchers concluded that RB-CPR should continue to be the recommended form of CPR for infants.

"Current public health campaigns focus on teaching compression-only CPR, and while this has improved outcomes in adults, it is possible this had disadvantaged children, particularly infants who did not show a benefit in outcome with compression-only CPR," explains Naim. "Bystander CPR education should continue to emphasize rescue breathing CPR for those under 18, especially infants, and teach lay rescuers how to perform rescue breathing CPR."

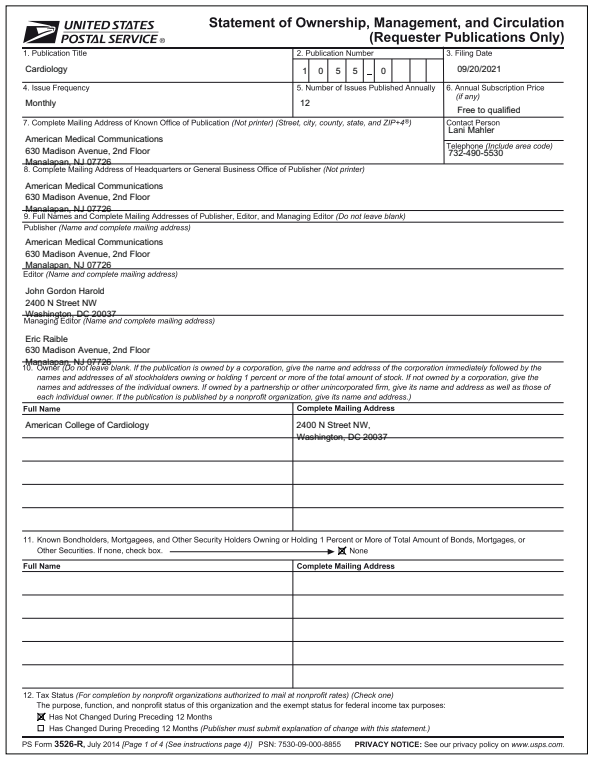
In a related editorial comment, **Gene Yong-Kwang Ong, MBBS,** explains, "Given that infants were consistently reported to suffer the worst clinical outcomes, and with this finding that bystander rescue breathing CPR could improve neurologically favorable survival, it behooves us to look into this in a timely manner. There needs to be important discussions in light of this data."

Naim MY, Griffis HM, Berg RA, et al. *J Am Coll Cardiol* 2021;78:1042-52.

CENTRAL ILLUSTRATION: Neurologically Favorable Survival and Cardiopulmonary Resuscitation Type in Infant, Children, and Adolescents



Naim, M.Y. et al. J Am Coll Cardiol. 2021;78(10):1042-1052.



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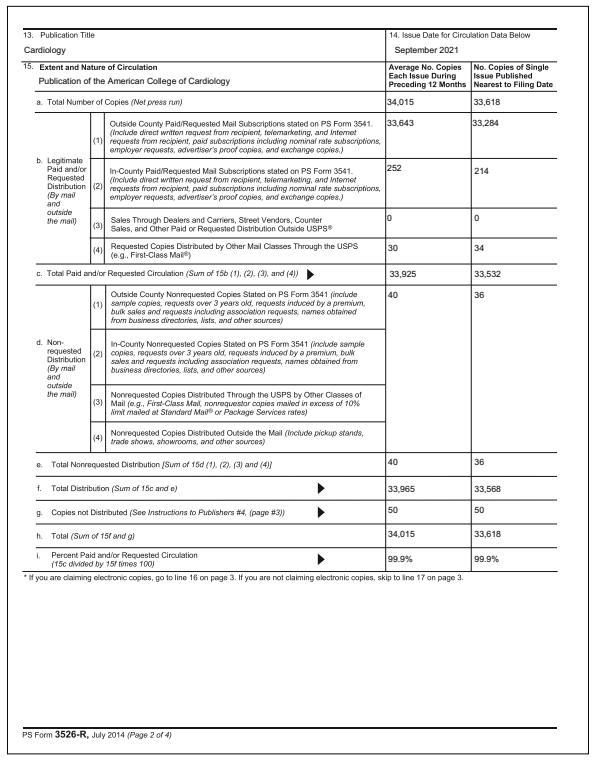

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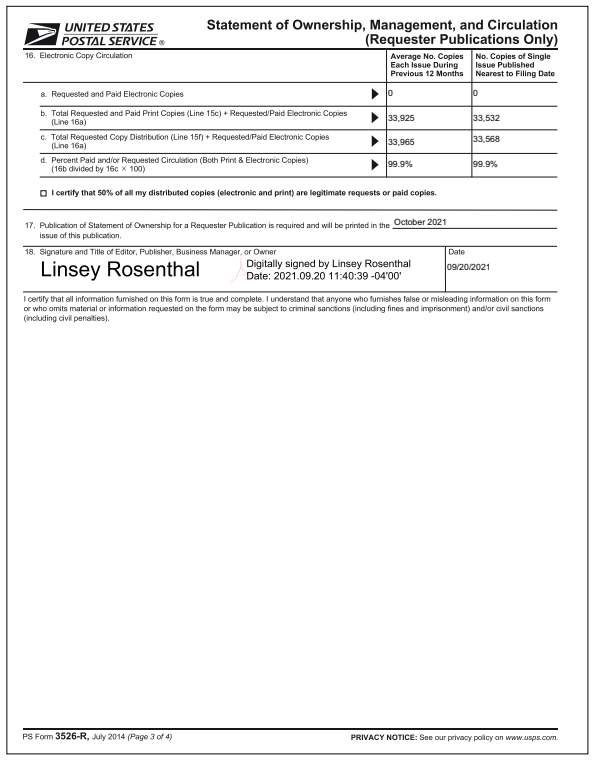

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LAAO Registry Study Shows **Women at Higher Risk** of Adverse Events After LAAO Procedure

Women may have a significantly higher risk of in-hospital adverse events following left atrial appendage occlusion (LAAO), according to a study published in *JAMA Cardiology*.

Douglas Darden, MD, et al., used data from ACC's LAAO Registry to look at sex differences in baseline characteristics among patients undergoing LAAO with the WATCHMAN device and in-hospital outcomes. The study's primary outcomes were aborted or canceled procedure, major adverse event, any adverse event, a hospital stay longer than one day and death.

The study cohort consisted of 49,357 patients with an average age of 76.1 years, 20,388 (41.3%) of whom were women and 28,969 (58.7%) were men. Men were more likely to be older and had a higher prevalence of paroxysmal atrial fibrillation, prior stroke and uncontrolled hypertension, but had a lower prevalence of congestive heart failure, diabetes and coronary artery disease.

The results show no differences in aborted or canceled procedures between women and men (3% vs. 2.9%). Women were more likely than men to experience a major adverse event (4.1% vs. 2%) or any adverse event (6.3% vs. 3.9%). Women also were more likely than men to require a hospital stay longer than one day (16% vs. 11.6%). In addition, although death was rare, it was more common among women than men (0.3% vs. 0.1%).

According to the researchers, women undergoing LAAO had a twofold higher risk of a major adverse event and a greater likelihood of experiencing any in-hospital event. They note that women comprise a larger proportion of patients receiving LAAO implants in real-world practice than in clinical trials, noting that the study's findings underscore the need to "continue to advocate for increased participation of women in clinical trials to better inform clinical decision-making and adequately delineate sex-based safety and efficacy outcomes." They conclude that additional research is needed to "identify the reasons for sex-based differences in outcomes and the strategies to reduce the risk of adverse events among women [undergoing LAAO]."

Darden D, Duong T, Du C, et al. *JAMA Cardiol* 2021;Aug.11:[Epub head of print].

Meta-Analysis Looks at **Prevalence of COPD in AFib**

Chronic obstructive pulmonary disease (COPD) is common in patients with atrial fibrillation (AFib), with an estimated prevalence of 13%, according to a large meta-analysis of nearly 50 international studies published in the *European Heart Journal*.

The AF-COMET International Collaborative Group reviewed data from more than 4.2 million patients with AFib to assess the prevalence of COPD, and its impact on clinical management and outcomes. The use of beta-blockers and associated impacts were explored.

COPD was associated with a greater number of comorbidities, older age, and higher CHA_2DS_2-VASc scores. COPD increased the risk of worse outcomes in AFib patients, including a twofold higher risk of all-cause mortality, increased risk of CV death and major bleeding. Beta-blockers were less frequently prescribed in patients with COPD and AFib but were not associated with increased risk of adverse outcomes.

Romiti GF, Corica B, Pipitone E, et al. *Eur Heart J* 2021;42:3541-54.

Scan the QR code to read more.

NEXLIZET® (bempedoic acid and ezetimibe) tablets
Professional Brief Summary. Please consult package insert for full Prescribing Information.

INDICATIONS AND USAGE
NEXLIZET is indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or established atherosclerotic cardiovascular disease who require additional lowering of LDL-C.
Limitations of Use: The effect of NEXLIZET on cardiovascular morbidity and mortality has not been determined.

CONTRAINDICATIONS
NEXLIZET is contraindicated in patients with a known hypersensitivity to ezetimibe tablets *[see Adverse Reactions]*. Hypersensitivity reactions including anaphylaxis, angioedema, rash and urticaria have been reported with ezetimibe.

WARNINGS AND PRECAUTIONS
Hyperuricemia
Bempedoic acid, a component of NEXLIZET, inhibits renal tubular OAT2 and may increase blood uric acid levels. In clinical trials, 26% of bempedoic acid-treated patients with normal baseline uric acid values (versus 9.5% placebo) experienced hyperuricemia one or more times, and 3.5% of patients experienced clinically significant hyperuricemia reported as an adverse reaction (versus 1.1% placebo). Increases in uric acid levels usually occurred within the first 4 weeks of treatment initiation and persisted throughout treatment. After 12 weeks of treatment, the mean placebo-adjusted increase in uric acid compared to baseline was 0.8 mg/dL for patients treated with bempedoic acid.
Elevated blood uric acid may lead to the development of gout. In clinical trials, gout was reported in 1.5% of patients treated with bempedoic acid and 0.4% of patients treated with placebo. The risk for gout events was higher in patients with a prior history of gout (11.2% bempedoic acid versus 1.7% placebo), although gout also occurred more frequently than placebo in patients treated with bempedoic acid who had no prior gout history (1.0% bempedoic acid versus 0.3% placebo).
Advise patients to contact their healthcare provider if symptoms of hyperuricemia occur. Assess serum uric acid when clinically indicated. Monitor patients for signs and symptoms of hyperuricemia, and initiate treatment with urate-lowering drugs as appropriate.
Tendon Rupture
Bempedoic acid, a component of NEXLIZET, is associated with an increased risk of tendon rupture or injury. In clinical trials, tendon rupture occurred in 0.5% of patients treated with bempedoic acid versus 0% of placebo-treated patients and involved the rotator cuff (the shoulder), biceps tendon, or Achilles tendon. Tendon rupture occurred within weeks to months of starting bempedoic acid. Tendon rupture may occur more frequently in patients over 60 years of age, in those taking corticosteroid or fluoroquinolone drugs, in patients with renal failure, and in patients with previous tendon disorders.
Discontinue NEXLIZET immediately if the patient experiences rupture of a tendon. Consider discontinuing NEXLIZET if the patient experiences joint pain, swelling, or inflammation. Advise patients to rest at the first sign of tendinitis or tendon rupture and to contact their healthcare provider if tendinitis or tendon rupture symptoms occur. Consider alternative therapy in patients with a history of tendon disorders or tendon rupture.

ADVERSE REACTIONS
The following clinically significant adverse reactions are described elsewhere in the labeling:
• Hyperuricemia *[see Warnings and Precautions]*
• Tendon Rupture *[see Warnings and Precautions]*
Clinical Trials Experience
Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.
Bempedoic acid: The data described below reflect exposure to bempedoic acid in two placebo-controlled trials that included 2009 patients treated with bempedoic acid for 52 weeks (median treatment duration of 52 weeks). The mean age for bempedoic acid-treated patients was 65.4 years, 29% were women, 3% were Hispanic, 95% White, 3% Black, 1% Asian, and 1% other races. All patients received bempedoic acid 180 mg orally once daily plus maximally tolerated statin therapy alone or in combination with other lipid-lowering therapies. At baseline, 97% of patients had clinical atherosclerotic cardiovascular disease (ASCVD) and about 4% had a diagnosis of heterozygous familial hypercholesterolemia (HeFH). Patients on simvastatin 40 mg/day or higher were excluded from the trials.
Adverse reactions led to discontinuation of treatment in 11% of bempedoic acid-treated patients and 8% of placebo-treated patients. The most common reasons for bempedoic acid treatment discontinuation were muscle spasms (0.5% versus 0.3% placebo), diarrhea (0.4% versus 0.1% placebo), and pain in extremity (0.3% versus 0.0% placebo). Adverse reactions reported in at least 2% of bempedoic acid-treated patients and more frequently than in placebo-treated patients are shown in Table 1.

Table 1. Adverse Reactions (≥2% and Greater than Placebo) in Bempedoic Acid-Treated Patients with ASCVD and HeFH

Adverse Reaction	Bempedoic acid + Statin and ± Other Lipid Lowering Therapies (N = 2009) %	Placebo (N = 999) %
Upper respiratory tract infection	4.5	4.0
Muscle spasms	3.6	2.3
Hyperuricemia[a]	3.5	1.1
Back pain	3.3	2.2
Abdominal pain or discomfort[b]	3.1	2.2
Bronchitis	3.0	2.5
Pain in extremity	3.0	1.7
Anemia	2.8	1.9
Elevated liver enzymes[c]	2.1	0.8

a. Hyperuricemia includes hyperuricemia and blood uric acid increased.
b. Abdominal pain or discomfort includes abdominal pain, abdominal pain upper, abdominal pain lower, and abdominal discomfort.
c. Elevated liver enzymes includes AST increased, ALT increased, hepatic enzyme increased, and liver function test increased.

Tendon Rupture
Bempedoic acid was associated with an increased risk of tendon rupture, occurring in 0.5% of bempedoic acid-treated patients versus 0% of placebo-treated patients.
Gout
Bempedoic acid was associated with an increased risk of gout, occurring in 1.5% of bempedoic acid-treated patients versus 0.4% of placebo-treated patients.
Benign Prostatic Hyperplasia
Bempedoic acid was associated with an increased risk of benign prostatic hyperplasia (BPH) or prostatomegaly in men with no reported history of BPH, occurring in 1.3% of bempedoic acid-treated patients versus 0.1% of placebo-treated patients. The clinical significance is unknown.
Atrial Fibrillation
Bempedoic acid was associated with an imbalance in atrial fibrillation, occurring in 1.7% of bempedoic acid-treated patients versus 1.1% of placebo-treated patients.
Laboratory Tests
Bempedoic acid was associated with persistent changes in multiple laboratory tests within the first 4 weeks of treatment. Laboratory test values returned to baseline following discontinuation of treatment.
Increase in Creatinine and Blood Urea Nitrogen: Overall, there was a mean increase in serum creatinine of 0.05 mg/dL compared to baseline with bempedoic acid at Week 12. Approximately 3.8% of patients treated with bempedoic acid had blood urea nitrogen values that doubled (versus 1.5% placebo), and about 2.2% of patients had creatinine values that increased by 0.5 mg/dL (versus 1.1% placebo).
Decreased Hemoglobin and Leukocytes: Approximately 5.1% of patients treated with bempedoic acid (versus 2.3% placebo) had decreases in hemoglobin levels of 2 or more g/dL and below the lower limit of normal on one or more occasion. Anemia was reported in 2.8% of patients treated with bempedoic acid and 1.9% of patients treated with placebo. Hemoglobin decrease was generally asymptomatic and did not require medical intervention. Decreased leukocyte count was also observed. Approximately 9.0% of bempedoic acid-treated patients with normal baseline leukocyte count had a decrease to less than the lower limit of normal on one or more occasion (versus 6.7% placebo). Leukocyte decrease was generally asymptomatic and did not require medical intervention. In clinical trials, there was a small imbalance in skin or soft tissue infections, including cellulitis (0.8% versus 0.4%), but there was no imbalance in other infections.
Increase in Platelet Count: Approximately 10.1% of bempedoic acid-treated patients (versus 4.7% placebo) had increases in platelet counts of 100×10^9/L or more on one or more occasion. Platelet count increase was asymptomatic, did not result in increased risk for thromboembolic events, and did not require medical intervention.
Increase in Liver Enzymes: Increases in hepatic transaminases (AST and/or ALT) were observed with bempedoic acid. In most cases, the elevations were transient and resolved or improved with continued therapy or after discontinuation of therapy. Increases to more than 3× the upper limit of normal (ULN) in AST occurred in 1.4% of patients treated with bempedoic acid versus 0.4% of placebo patients, and increases to more than 5× ULN occurred in 0.4% of bempedoic acid-treated versus 0.2% of placebo-treated patients. Increases in ALT occurred with similar incidence between bempedoic acid- and placebo-treated patients. Elevations in transaminases were generally asymptomatic and not associated with elevations ≥2× ULN in bilirubin or with cholestasis.
Increase in Creatine Kinase: Approximately 1.0% of patients (versus 0.6% placebo) had elevations of CK levels of 5 or more times the normal value on one or more occasions, and 0.4% of patients (versus 0.2% placebo) had elevations of CK levels of 10 or more times.
Ezetimibe: In 10 double-blind, placebo-controlled clinical trials, 2396 patients with primary hyperlipidemia (age range 9-86 years, 50% women, 90% Caucasians, 5% Blacks, 3% Hispanics, 2% Asians) and elevated LDL-C were treated with ezetimibe 10 mg/day for a median treatment duration of 12 weeks (range 0 to 39 weeks).
Adverse reactions led to discontinuation of treatment in 3.3% of ezetimibe-treated patients and 2.9% of placebo-treated patients. The most common reasons for ezetimibe treatment discontinuation were arthralgia (0.3%), dizziness (0.2%), and gamma-glutamyltransferase increased (0.2%). Adverse reactions reported in ≥2% of patients treated with ezetimibe and at an incidence greater than placebo in placebo-controlled studies of ezetimibe, regardless of causality assessment, are shown in Table 2.

Table 2. Clinical Adverse Reactions Occurring in ≥ 2% of Patients Treated with Ezetimibe and at an Incidence Greater than Placebo, Regardless of Causality

Adverse Reaction	Ezetimibe 10 mg (%) N = 2369	Placebo (%) N = 1159
Upper respiratory tract infection	4.3	2.5
Diarrhea	4.1	3.7
Arthralgia	3.0	2.2
Sinusitis	2.8	2.2
Pain in extremity	2.7	2.5
Fatigue	2.4	1.5
Influenza	2.0	1.5

The frequency of less common adverse reactions was comparable between ezetimibe and placebo.
NEXLIZET: In a 4-arm, 12-week, randomized, double-blind, placebo-controlled, parallel group, factorial trial, 85 patients received NEXLIZET (180 mg of bempedoic acid and 10 mg of ezetimibe) once daily. The mean age for NEXLIZET-treated patients was 62 years, 51% were women, 12% Hispanic, 78% White, 19% Black, and 2% Asian. At baseline, 61% of patients had clinical atherosclerotic cardiovascular disease (ASCVD) and/or a diagnosis of heterozygous familial hypercholesterolemia. All patients received NEXLIZET plus maximally tolerated statin therapy. Patients taking simvastatin 40 mg/day or higher and patients taking non-statin lipid-lowering therapy (including fibrates, niacin, bile acid sequestrants, ezetimibe, and PCSK9 inhibitors) were excluded from the trial.
Adverse reactions led to discontinuation of treatment in 8% of patients on NEXLIZET, 5% of patients on placebo, 10% of patients on bempedoic acid, and 12% of patients on ezetimibe. The most common reason for NEXLIZET treatment discontinuation was oral discomfort (2% NEXLIZET versus 0% placebo). The most commonly reported adverse reactions (incidence ≥3% and greater than placebo) observed with NEXLIZET, but not observed in clinical trials of bempedoic acid or ezetimibe, were urinary tract infection (5.9% NEXLIZET versus 2.4% placebo), nasopharyngitis (4.7% NEXLIZET versus 0% placebo), and constipation (4.7% NEXLIZET versus 0% placebo).

NCDR Research: Non-Evidence-Based ICD Implantation Associated With Increased Risk of Mortality, Readmissions

Patients who received non-evidence-based ICDs for primary prevention had an increased risk of mortality and hospitalization, according to a study published recently in the *American Journal of Cardiology*. Researchers observed the greatest increase in risk occurred within the first year of device implantation.

The retrospective analysis evaluated data from 71,555 ICD implantations identified in ACC's EP Device Implant Registry, formerly the ICD Registry, and linked to Medicare fee-for-service administrative claims data between April 2010 and December 2013. Of these, 9,609 (13.4%) were categorized as non-evidenced based, defined as primary prevention-based implantation in patients with recent myocardial infarction (MI) or coronary revascularization and those with newly diagnosed or severe heart failure (HF). **Usama A. Daimee, MD,** et al., used multivariable time-to-even analyses to compare longitudinal outcomes, including all-cause mortality and all-cause hospital readmissions, over an average of 4.75 years following ICD implantation.

Overall results found that patients receiving non-evidence-based ICDs had greater mortality risk at 90 days and at one year compared with those receiving evidence-based ICDs. Mortality risk was similar across both groups at three years. Similarly, patients in the non-evidence-based ICD group had a greater risk of all-cause hospital readmissions at 90 days; however, researchers noted the difference in readmission risk between the evidence-based and non-evidence-based groups decreased at one year and three years.

"The increased risk of mortality and hospitalization in patients with non-evidence-based ICDs was observed early in follow-up and largely in patients with NYHA Class IV symptoms and those with MI within 40 days," said Daimee and colleagues. "These findings may help guide shared decision-making for ICD implantations, particularly for severe HF patients and those recovering from a recent MI."

Daimee UA, Aslam F, Parzynski CS, et al. *Am J Cardiol* 2021;155:64-71.

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Postmarketing Experience
Because these reactions are reported voluntarily from a population of uncertain size, it is generally not possible to reliably estimate their frequency or establish a causal relationship to drug exposure.
The following additional adverse reactions have been reported in postmarketing experience for ezetimibe:
Hypersensitivity reactions, including anaphylaxis, angioedema, rash, and urticaria; erythema multiforme; myalgia; elevated creatine phosphokinase; myopathy/rhabdomyolysis; elevations in liver transaminases; hepatitis; abdominal pain; thrombocytopenia; pancreatitis; nausea; dizziness; paresthesia; depression; headache; cholelithiasis; cholecystitis.

DRUG INTERACTIONS
No specific pharmacokinetic drug interaction studies with NEXLIZET have been conducted. Drug interactions that have been identified in studies with bempedoic acid or ezetimibe determine the interactions that may occur with NEXLIZET.
Simvastatin: *Clinical Impact:* Concomitant use of NEXLIZET with simvastatin causes an increase in simvastatin concentration and may increase the risk of simvastatin-related myopathy. *Intervention:* Avoid concomitant use of NEXLIZET with simvastatin greater than 20 mg.
Pravastatin: *Clinical Impact:* Concomitant use of NEXLIZET with pravastatin causes an increase in pravastatin concentration and may increase the risk of pravastatin-related myopathy. *Intervention:* Avoid concomitant use of NEXLIZET with pravastatin greater than 40 mg.
Cyclosporine: *Clinical Impact:* Concomitant use of NEXLIZET and cyclosporine increases ezetimibe and cyclosporine concentrations. *Intervention:* Monitor cyclosporine concentrations in patients receiving NEXLIZET and cyclosporine. In patients treated with cyclosporine, the potential effects of the increased exposure to ezetimibe from concomitant use should be carefully weighed against the benefits of alterations in lipid levels provided by NEXLIZET.
Fibrates: *Clinical Impact:* Both fenofibrate and ezetimibe may increase cholesterol excretion into the bile, leading to cholelithiasis. Coadministration of NEXLIZET with fibrates other than fenofibrate is not recommended. *Intervention:* If cholelithiasis is suspected in a patient receiving NEXLIZET and fenofibrate, gallbladder studies are indicated and alternative lipid-lowering therapy should be considered.
Cholestyramine: *Clinical Impact:* Concomitant use of NEXLIZET and cholestyramine decreases ezetimibe concentration. This may result in a reduction of efficacy. *Intervention:* Administer NEXLIZET either at least 2 hours before or at least 4 hours after bile acid sequestrants.

USE IN SPECIFIC POPULATIONS
Pregnancy
Risk Summary
Discontinue NEXLIZET when pregnancy is recognized unless the benefits of therapy outweigh the potential risks to the fetus.
There are no available data on bempedoic acid use in pregnant women to evaluate for a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes.
There are insufficient data on ezetimibe use in pregnant women to evaluate for a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes.
In animal reproduction studies, bempedoic acid was not teratogenic in rats and rabbits when administered at doses resulting in exposures up to 11 and 12 times, respectively, the human exposures at the maximum clinical dose, based on AUC. In oral (gavage) embryo-fetal development studies of ezetimibe conducted in rats and rabbits during organogenesis, there was no evidence of maternal toxicity or embryo-fetal teratogenic or toxicologic effects at exposures up to 10 and 150 times the human exposure, respectively, based on AUC *(see Data)*.
NEXLIZET decreases cholesterol synthesis and possibly the synthesis of other biologically active substances derived from cholesterol; therefore, NEXLIZET may cause fetal harm when administered to pregnant women based on the mechanism of action. In addition, treatment of hyperlipidemia is not generally necessary during pregnancy. Atherosclerosis is a chronic process and the discontinuation of lipid-lowering drugs during pregnancy should have little impact on the outcome of long-term therapy of primary hyperlipidemia for most patients.
The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively.
Data
Animal Data
Bempedoic acid
Bempedoic acid was not teratogenic when given orally at doses of 60 and 80 mg/kg/day, resulting in 11 and 12 times the systemic exposure in humans at the maximum recommended human dose (MRHD) of 180 mg to pregnant rats and rabbits, respectively. In an embryofetal development study in rats, bempedoic acid was given orally to pregnant rats at 10, 30, and 60 mg/kg/day during the period of organogenesis from gestation day 6 to 17. There were increases in the incidence of non-adverse fetal skeletal variations (bent long bones and bent scapula and incomplete ossification) at doses ≥ 10 mg/kg/day (less than the clinical exposure) in the absence of maternal toxicity. At maternally toxic doses, bempedoic acid caused decreases in the numbers of viable fetuses, increases in post-implantation loss, and increased total resorptions at 60 mg/kg/day (11 times MRHD) and reduced fetal body weight at ≥ 30 mg/kg/day (4 times the MRHD). No adverse development effects were observed when bempedoic acid was given to pregnant rabbits during the period of organogenesis (gestation day 6 to 18) at doses up to 80 mg/kg/day (12 times MRHD).
In a pre- and post-natal development study in pregnant rats given oral doses of bempedoic acid at 5, 10, 20, 30 and 60 mg/kg/day throughout pregnancy and lactation (gestation day 6 to lactation day 20), there were adverse effects on delivery in the presence of maternal toxicity, including: increases in stillborn pups, reductions in numbers of live pups, pup survival, pup growth and slight delays in learning and memory at ≥ 10 mg/kg/day (at exposures equivalent to the MRHD).
Ezetimibe
In oral (gavage) embryo-fetal development studies of ezetimibe conducted in rats (gestation days 6-15) and rabbits (gestation days 7-19) during organogenesis, there was no evidence of maternal toxicity or embryolethality at any of the doses tested (250, 500, 1000 mg/kg/day) at exposures equivalent to 10 to 150 times the MRHD, based on AUC, in rats and rabbits. In rats, increased incidences of common fetal skeletal findings (extra pair of thoracic ribs, unossified cervical vertebral centra, shortened ribs) were observed at 1000 mg/kg/day (approximately 10 times the human exposure at 10 mg daily based on $AUC_{0\text{-}24hr}$ for total ezetimibe). In rabbits treated with ezetimibe, an increased incidence of extra thoracic ribs was observed at 1000 mg/kg/day (150 times the human exposure at 10 mg daily based on $AUC_{0\text{-}24hr}$ for total ezetimibe). The animal-to-human exposure multiple for total ezetimibe at the no-observed effect level was 6 times for rat and 134 times for rabbit.
Fetal exposure to ezetimibe (conjugated and unconjugated) was confirmed in subsequent placental transfer studies conducted using a maternal dose of 1000 mg/kg/day. The fetal maternal plasma exposure ratio (total ezetimibe) was 1.5 for rats on gestation day 20 and 0.03 for rabbits on gestation day 22.
The effect of ezetimibe on prenatal and postnatal development and maternal function was evaluated in pregnant rats at doses of 100, 300 or 1000 mg/kg/day (gestation day 6 through lactation day 21). No maternal toxicity or adverse developmental outcomes were observed up to and including the highest dose tested (17 times the human exposure at 10 mg daily based on $AUC_{0\text{-}24hr}$ for total ezetimibe).
Multiple-dose studies of ezetimibe coadministered with statins in rats and rabbits during organogenesis result in higher ezetimibe and statin exposures. Reproductive findings occur at lower doses in combination therapy compared to monotherapy.
Bempedoic acid/ezetimibe fixed combination drug product (FCDP)
In a combination embryofetal development study in rats, bempedoic acid and ezetimibe were given orally at 4 and 112-times MRHD (based on AUC) during the period of organogenesis (gestation day 6 to 17) in pregnant rats. Bempedoic acid in combination with ezetimibe did not alter the effects on embryo-fetal development profile of bempedoic acid or ezetimibe.
Lactation
Risk Summary
There is no information regarding the presence of bempedoic acid in human or animal milk, the effects of the drug on the breastfed infant, or the effects of the drug on milk production. There is no information about the presence of ezetimibe in human milk. Ezetimibe is present in rat milk (*see Data*). When a drug is present in animal milk, it is likely that the drug will be present in human milk. There is no information about the effects of ezetimibe on the breastfed infant or the effects on milk production.
NEXLIZET decreases cholesterol synthesis and possibly the synthesis of other biologically active substances derived from cholesterol and may cause harm to the breastfed infant. Because of the potential for serious adverse reactions in a breastfed infant, based on the mechanism of action, advise patients that breastfeeding is not recommended during treatment with NEXLIZET.
Data
Animal Data
Ezetimibe was present in the milk of lactating rats. The pup to maternal plasma ratio for total ezetimibe was 0.5 on lactation day 12.
Pediatric Use
The safety and effectiveness of NEXLIZET have not been established in pediatric patients.
Geriatric Use
Of the 301 patients in the clinical trial of NEXLIZET, 149 (50%) were 65 and over, while 49 (16%) were 75 and over. No overall differences in safety or effectiveness were observed between these patients and younger patients, and other reported clinical experience has not identified differences in responses between the elderly and younger patients. However, greater sensitivity of some older individuals cannot be ruled out.
Renal Impairment
No dosage adjustment is necessary for NEXLIZET in patients with mild or moderate renal impairment. There is limited experience with bempedoic acid in patients with severe renal impairment (eGFR < 30 mL/min/1.73 m^2), and it has not been studied in patients with end-stage renal disease (ESRD) receiving dialysis.
Hepatic Impairment
No dosage adjustment is necessary for NEXLIZET in patients with mild hepatic impairment (Child-Pugh A). NEXLIZET is not recommended in patients with moderate or severe hepatic impairment (Child-Pugh B or C) due to the unknown effects of the increased exposure to ezetimibe.

OVERDOSAGE
There is no clinical experience with NEXLIZET overdosage. In the event of overdose, contact Poison Control (1-800-222-1222) for latest recommendations.

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Based on NEXLIZET Prescribing Information
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Overcoming Vaccine Hesitancy

Helping Patients Help Themselves

More than one-third of unvaccinated individuals in the U.S. believe risks from the vaccine are greater than the risk of COVID-19.

Vaccine hesitancy – the reluctance or refusal to receive a vaccine despite its availability – is nothing new. Hesitation and even opposition to vaccines began shortly after the introduction of the smallpox vaccination in the 1800s and have continued ever since. In fact, the World Health Organization (WHO) listed vaccine hesitancy as one of the top 10 threats to global health back in 2019.

The reasons for vaccine hesitancy are varied. For some, a fear of needles, concerns about missing work, or anxiety regarding side effects are behind decisions to delay or avoid a vaccine. For others, the reasons can be more complex and tied to deep-seated spiritual, religious, philosophical and/or political beliefs of individuals, thus making conversations about vaccines all the more difficult.

While the debate over vaccines hasn't waned over the last two centuries, the COVID-19 pandemic has definitely brought it to the forefront as death tolls from the virus continue to rise and countries around the world continue to roll out the vaccine. According to Our World in Data, only about 44% of the world population had received at least one dose of a COVID-19 vaccine as of September, with the vast majority of vaccinated individuals living in higher-income countries. Only 2% of people living in low-income countries have had at least one dose of the vaccine. Meanwhile, the global death toll has reached more than 4.5 million and counting.

Outside of access to the vaccine – which is clearly one of the top reasons for low vaccination numbers, particularly in low-income countries – vaccine hesitancy is another major contributor. Concerns about the safety of the vaccine, given the lack of long-term data and the speed of development and authorization for use, are often cited. For example, more than one-third of unvaccinated individuals in the U.S. believe risks from the vaccine are greater than the risk of COVID-19, according to data from the Kaiser Family Foundation. Similarly, a recent poll conducted by the de Beaumont Foundation found that one-third of nearly a thousand unvaccinated adults said full approval by the U.S. Food and Drug Administration (FDA) would address all or most of their concerns about the vaccines' safety, while another 20% said it would address some of their concerns.

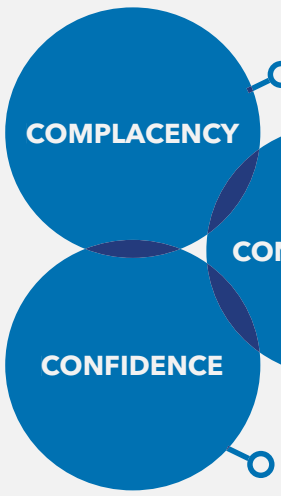
> **"It's critical that cardiologists talk with their patients about vaccine hesitancy."**
>
> **Gladys Velarde, MD, FACC**

Religious beliefs, concerns about government mandates on health care decisions and civil liberties, and lack of public trust in government and research, especially among certain racial and ethnic groups, are also playing a role in the vaccine debate. Layer on complacency with the status quo and all the misinformation and disinformation (i.e., alteration of DNA myths and microchip and 5G conspiracy theories) that are easily propagated and spread through social media platforms and the internet, and there's a powerful vortex that continues to keep too many individuals on the sidelines, not getting vaccinated.

Scan the QR code for a tip sheet for communicating about the FDA approval to build confidence in the vaccine.

Understanding the "3 Cs" Model of Vaccine Hesitancy

The "3 Cs" model outlines how complacency, confidence and convenience play into vaccine hesitancy. Addressing concerns within these domains can help with moving patients along the spectrum from resistance or hesitancy to accepting a vaccine.



COMPLACENCY — Perceived risks of vaccine-preventable diseases are low; vaccination is not deemed a necessary preventative action. Other life/health responsibilities seen as more important at that point in time.

CONVENIENCE — Extent to which physical availability, affordability, willingness -to-pay, geographical accessibility, ability to understand (language and health literacy) and appeal of immunization services affects uptake.

CONFIDENCE — Trust in vaccines, in the system that delivers them, and in the policy makers who decide which vaccines are needed and when.

Source: MacDonald & SAGE Working Group on Vaccine Hesitancy. Vaccine 2015;33:4161-4.

Who Do You Trust?

How do we solve for this dilemma, given the very real scientific evidence showing the ability of the vaccine to save lives, reduce hospitalizations and slow the spread of the virus? Enter the role of health care providers, who are viewed as trusted sources of information when it comes to decisions about vaccines, disease management and overall health.

"The government and the media have tried to encourage people to get a vaccine. Yet, many times patients want to hear directly from their own caregivers about the risks and benefits of having a vaccine," says **Ami Bhatt, MD, FACC,** director of the Massachusetts General Hospital's Adult Congenital Heart Disease Program in Boston. "Having the discussion with somebody in the medical field who knows them and who recommends the shot was more than enough to convince many of my patients to get a vaccine," she says.

This trust in health care providers hasn't been lost on groups like the WHO, which have made it a priority to help increase public trust in health care clinicians and health systems to combat misinformation and improve patient outcomes – whether it's combatting COVID-19 or dramatically reducing noncommunicable diseases like cardiovascular disease and cancer, which account for 71% of all deaths globally.

"At times it can seem like a daunting task to even ask a patient if they have been vaccinated or to test the waters about their willingness to discuss why not and engage them in a conversation that may help them make a different choice," says Bhatt, "but with the uptake of COVID-19 vaccines stalling, and the numbers of people infected and dying, it's falling to individual conversations between clinicians and patients to move the needle, one at a time."

Gladys Velarde, MD, FACC, professor and medical director of the Women's Cardiovascular Heart Program at the University of Florida in Jacksonville, agrees. "It's critical that cardiologists talk with their patients about vaccine hesitancy," says Velarde, noting the need to treat the whole patient, not just one condition. "When I speak with patients, I make it very clear their chronic conditions could lead to a worse outcome if they get infected."

> **"The government and the media have tried to encourage people to get a vaccine. Yet, many times patients want to hear directly from their own caregivers about the risks and benefits of having a vaccine."**
>
> Ami Bhatt, MD, FACC

Vaccine Education Resources For Patients

ACC's CardioSmart initiative includes infographics and other patient tools in multiple languages to help educate heart patients about COVID-19 and the importance of vaccines.

Greater Than COVID is a public information initiative led by the Kaiser Family Foundation that provides Vaccine FAQ videos featuring a diverse range of physicians, nurses, community health workers and trusted leaders answering questions about the COVID-19 vaccine, including new variants, safety and why young healthy people need it too. Videos are also available in Spanish.

FDA Vaccine Information is available on the FDA website in a number of languages, including Spanish, Portuguese, Chinese, Korean, Tagalog and Somali.

The Vaccine Confidence Project started a decade ago to monitor public confidence in immunization programs and provide analysis and guidance for early response and engagement with the public. Scan the QR code for polling and resources.

> **While COVID-19 didn't cause these underlying disparities, it unmasked and revealed them because it placed these patient populations at higher risk.**
>
> Keith C. Ferdinand, MD, FACC

Diverse Populations, Diverse Concerns

In both the Latinx and Black communities, the rates of risk factors, comorbidities and cardiovascular disease are higher compared with Whites. "While COVID-19 didn't cause these underlying disparities, it unmasked and revealed them because it placed these patient populations at higher risk," says **Keith C. Ferdinand, MD, FACC.** Death rates from COVID-19 were ninefold higher in Blacks than Whites in March 2021, while they were fourfold higher for American Indians and Alaska Natives and threefold higher for Latinx Americans.[1]

Meanwhile, vaccination uptake for COVID-19 in these communities continues to be lower, compared with Whites. While there are some signs of a recent uptick in vaccination rates across all racial and ethnic groups, the rates of vaccination still fall far short in relation to the share of COVID-19 infection in most of these communities.

What are some of the reasons behind these trends? Within the African American/ Black community, a long-standing mistrust of orthodox medicine is a major barrier to accepting vaccinations, says Ferdinand. The Tuskegee syphilis study, where Black men were deliberately not treated for syphilis for research purposes, and the infamous case of Henrietta Lacks, whose cancer cells were used by scientists without her knowledge, are two prominent drivers of this mistrust.

Velarde notes a similar widespread mistrust of the government and the medical system within the Latinx community, in addition to frequent language barriers and often limited access to regular care. "The Latinx community uses a lot of social media, which has been inundated with misinformation that creates mistrust and fear," she says. For example, misinformation about proof of citizenship requirements has held undocumented workers back from vaccination, while rumors about fertility impacts, DNA alteration and microchips are also adding to vaccine hesitancy in this patient population.

Language barriers and lack of information about the vaccine, rather than misinformation, is a common problem in Asian communities that are also disproportionately impacted by COVID-19, says **Eugene Yang, MD, FACC,** professor of medicine and Carl and Renée Behnke Endowed Professor for Asian Health at the University of Washington School of Medicine in Seattle. More recently, concerns about hate-related violence have also meant many Asian Americans are afraid of leaving their homes or communities out of fear of being attacked. Research from the Pew Research Center published this past March said 26% of Asian Americans surveyed feared being threatened or attacked in the last year.

Personalizing Solutions

When Ferdinand met recently with a younger, Black immunocompromised patient the first question to the patient was whether he'd been vaccinated for COVID-19. Because the patient was at high risk, addressing an immediate barrier to his ongoing health came before the usual cardiac evaluation, Ferdinand says.

As with all his vaccine-hesitant patients, Ferdinand, a cardiologist and professor of clinical medicine at the Tulane University Heart and Vascular Institute in New Orleans, listened without judgment to the man's fears and then was able to engage in a conversation and provide important resources on the vaccine's safety, as well as the very real risks of death should the patient remain unvaccinated and be diagnosed with COVID-19. "I think understanding the potential impacts on his life and his family helped him to recognize the need to protect himself and get vaccinated," he says.

Ferdinand, who is also a member of the National Institutes of Health's Community Engagement Alliance (CEAL) Against COVID-19 Disparities and the Louisiana COVID-19 Health Equity Task Force, also shares with patients the South African concept of Ubuntu, which recognizes that everyone within a community is connected. "Although there seems to be a concept afloat that whether or not to get vaccinated is one's personal

COVID-19 and Asian Americans

The high morbidity and mortality rate associated with Asians and COVID-19 is probably a combination of many different factors," according to Yang, who is also a member of the global faculty of the Stanford Center for Asian Health Research and Education.

He notes that some comorbidities like hypertension or high cholesterol are more prevalent in certain Asian subgroups, which could put those specific groups at higher risk for death or hospitalization from COVID-19. He also points out that Asian Americans, similar with Latinx communities, are likely to have increased COVID-19 exposure because many live in crowded multigenerational housing. Unique to the Asian American population, 20% of individuals live in a household with at least one health care worker, which also means greater exposure to the virus.

While the good news is that Asian Americans broadly have a relatively high vaccination rate – they make up 6% of the population and they have received 6% of vaccines – poor quality data and a lack of disaggregated race/ethnicity data are obscuring COVID-19-related disparities.

"The key problem is that Asians are lumped together in one group, and the impact of COVID-19 and vaccination rates are much more subtle than that," says Yang. He hopes that future data collection can be expanded to better understand the subtleties across Asian populations and better target and manage care and vaccination efforts.

Scan the QR code for CardioSmart COVID-19 patient education in several different languages.

choice, in reality, with infectious diseases, it's everyone's business. This is especially true for coronavirus infections that are spread through droplets and aerosols and prolonged contact." According to Ferdinand, when individuals are able to recognize that the disproportionate rate of hospitalization and death are real, not imagined, they are more willing to see the value and the role they can play in helping themselves, their families and their community.

Health care providers working in tandem with community leaders and organizations have also proven to be successful tactics in reaching Black, Latinx and Asian communities. Yang notes that community events to book appointments have been successful in overcoming technology and language barriers and reaching specific Asian communities across the country, such as Hmong communities in Minnesota or Korean communities in Seattle.

Community partnerships can also help provide translating services and/or distribute information where people live, work, worship and play. Yang notes that when he sees vaccine-hesitant patients who don't speak fluent English, he makes sure to rely on translators and to hand out information sheets in their native language.

Velarde uses similar tactics with her Latinx patients. She was one of the first in Florida in line for the COVID-19 vaccine and shares that photo of herself in the newspaper with her patients and during Spanish-speaking community vaccination events where she's a volunteer. She takes the time to listen to and address the concerns of those who are hesitant about vaccination and has handouts ready to give them to take home.

If a patient agrees to get a COVID-19 vaccine, Velarde arranges for a medical assistant to take the patient to the hospital's vaccination clinic directly after the visit. Encouraging patients to get vaccinated is a team effort, she says, and she reminds staff that accompanying someone to the clinic is just as important as taking the patient's vitals.

> **"Education, education, education, verbal and written, is needed to reach specific populations about the benefit of COVID-19 vaccination."**
>
> Gladys Velarde, MD, FACC

"Education, education, education, verbal and written, is needed to reach specific populations about the benefit of COVID-19 vaccination," says Velarde. She also urges clinicians not to underestimate the value of community volunteering. "Volunteering shouldn't stop in medical school," she says. "It's important for clinicians to have a wider breadth of knowledge of what it means to take care of our citizens."

REFERENCE

1. Quinn SC, Andrasik MP. *N Engl J Med* 2021;385:97-100.

Trust-Building Tips

- **Use storytelling.** "It's more impactful when a doctor shares what they have witnessed as opposed to talking about what they read in a medical journal or the latest CDC recommendations," says Mark Miller, vice president of communications at the de Beaumont Foundation, which focuses on public health. "It's not about statistics, it's about making it real." It's also not about trying to convert a patient. "If you come across as judgmental or condescending or frustrated then they're going to dig in deeper," he says. Also, choose your words carefully, framing things positively, for example in terms of benefit rather than consequences. Sometimes a single word can make a difference.
- **Provide credible resources.** For some patients, local sources are trusted more than national ones. And local trusted leaders may be one of the most important partners for overcoming vaccine hesitancy. Steer patients to recognized sources, like the ACC and American Heart Association, and have handouts prepared for them in their language they can take home. Remind patients not all health information on the internet is fact-based, and some is opinion-based dressed up as medically based (for example, an osteopathic physician considered the number one spreader of misinformation on this topic has published over 600 articles that cast doubt on COVID-19 vaccines.)
- **Focus on the Middle.** Some 10% of people are in the "wait and see" category when it comes to making their decision about getting vaccinated against COVID-19, according to a poll conducted in July by the Kaiser Family Foundation. It's this watchful waiter group that is most open to talking about the vaccine and most likely moveable.

Scan the QR code for a COVID-19 Vaccine Monitor dashboard with more detailed information by demographics, a daily tracker, and a section on tailoring the conversation to different groups.

- **Know When to Concede.** At times, says Bhatt, it's necessary to concede a patient is unlikely to be moved. "Forcing people to see your way is never a way to have that conversation," she says. "Try to understand why they are hesitant and answer their questions to the best of your scientific ability, and then use your rapport to help them come to a place where they are willing to think about it more."

Online Toolkit

Don't miss the additional tips and resources to guide conversations with patients about the COVID-19 vaccine with the online version of this article at *ACC.org/Cardiology*.

HERE ARE 6 THINGS YOU CAN DO TO IMPROVE VACCINE ACCEPTANCE AMONG YOUR PATIENT FAMILIES.

1. **Lead by example.** Get vaccinated and encourage your entire staff to be vaccinated.
2. **Prepare your health care team, pharmacy teams, and staff to have these conversations.** Ask your staff if they'd be willing to speak with patients and other staff about why they got vaccinated. All staff should be equipped to answer basic questions about COVID vaccines.
3. **Share educational materials widely.** Post information in the waiting room, the staff break room, and common areas in your facility. Publish information on your website, intranet, and social media platforms. Include a way for people to contact you with questions.
4. **During patient visits, make the COVID-19 vaccine a new vital sign.** Ask every patient what their vaccination plan is. For those who say they will take it, make sure they know how and where to schedule an appointment. If they say they're not sure, discuss their concerns and answer their questions.
5. **Partner with your health department, employers, and others to engage with community members.** Collaborate with trusted messengers – like faith-based leaders, local employers, and other community leaders – to tailor and share culturally relevant messages and materials.
6. **Consider sending a letter or email to your patients.** Start by expressing your concern for the health of your patients and their loved ones. Provide facts, refer them to additional resources, and offer to answer questions. See sample language on page 4.

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The Power of Real Conversations in a Social Media World

Medical misinformation has long found a home on the internet. Misleading stories on statins are almost as old as the internet itself. Still, the advent of social media materially changed the game. Instead of needing to proactively search for information, networks and algorithms often now push dubious and sometimes downright dangerous information into feeds. Like it or not, we're all part of what social scientists call the information wars, a strange and shadowy entanglement of culture, politics and power, all fought online through information and disinformation. Often the first victim of this virtual fracas is what was once regarded as commonly held truths, an especially grave concern when it comes to scientific or medical facts. How are cardiologists supposed to navigate this larger social phenomenon without getting drawn into the scuffle?

Eric Stecker, MD, FACC, chair of ACC's Science and Quality Committee and a cardiologist at Oregon Health and Science University, has thought long and hard about this problem, likening it to his career-long efforts to encourage his patients to quit smoking. "I start by asking every patient at every visit about their COVID-19 vaccine status, regardless of their personal risk, and take it from there," he says. "Just like smoking, this is something so important to cardiovascular and overall health that it is the responsibility of all of us. We can't just leave it to our primary care colleagues."

If a patient isn't vaccinated, Stecker assesses their level of readiness or resistance. I often raise the issue of social media myself, asking if they've read or heard anything online that worries them," he says. Stecker emphasizes the importance of getting the conversation going and avoiding politicizing the discussion. He's learned to use less-loaded terms like "rumors," "inaccuracies," or "confusion," to help make space for the vaccine-hesitant to modify their thinking.

Sometimes Stecker can tell it's a lost cause. "I know that if I keep pushing I might jeopardize my whole relationship with the patient. Or I spend too much time fruitlessly addressing vaccination to the detriment of other important aspects of their care.

But just as often, acknowledging all the confusion out there makes space for a genuine conversation. Stecker always steers the conversation back to the scientific facts but in a way that humanizes the discussion and leverages the trust he has earned with his patients. "I tell them that I have looked into the issue personally and studied the data. I tell them I believe the vaccine is safe, for myself, for my family and for my patients. I tell them I think it will help keep them safe and healthy," he says. It doesn't work every time, but Stecker is proud to recall when his vaccine-hesitant patients have ultimately gone on to receive the shot. "I know it's more than my effort, but hopefully my effort has made a difference.

Using "OARS" to Navigate Vaccine Hesitancy Waters

Motivational interviewing is one behavioral change strategy that could help patients who are hesitant about vaccinations. The following "OARS" strategy can help identify concerns and encourage action.

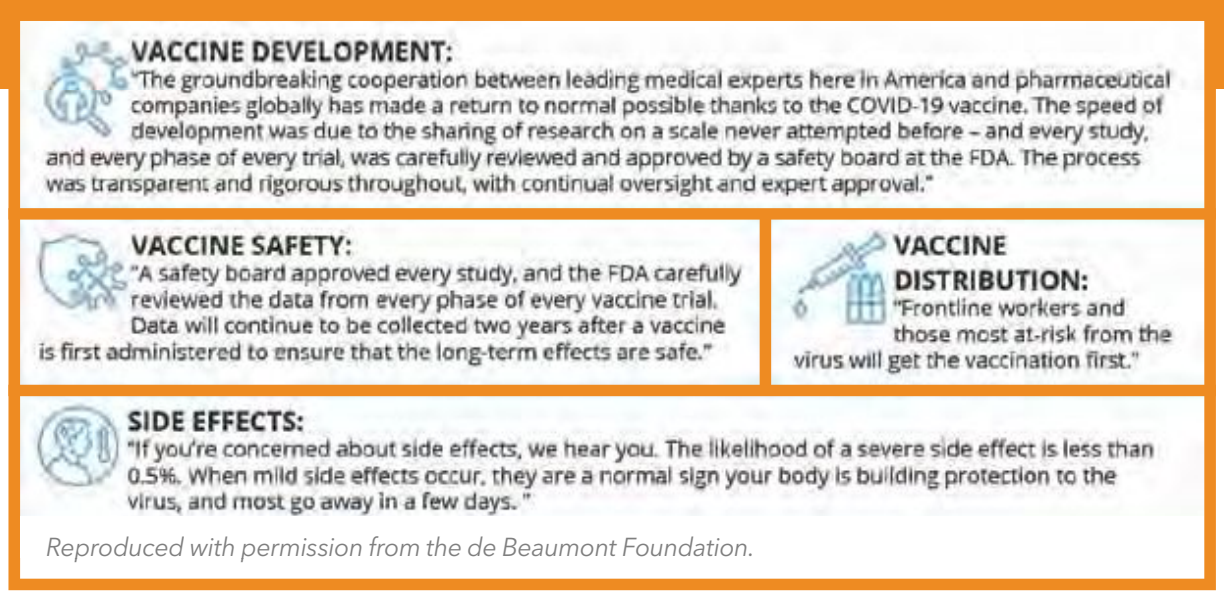
O: Ask **open-ended questions** instead of yes/no questions. For example, "If you had one habit that you wanted to change to improve your health, what would it be?"

A: Use **affirmations**. When you review patients' goals, show joy in their successes and express empathy during tough spots.

R: Adopt **reflective listening** techniques. After patients express their thoughts and concerns, capture the essence of what was said, which can keep the conversation moving and help them arrive at an idea for change. For example, "You commented that you have some older family members you want to visit but need to keep them safe, and that you have some questions about the vaccine."

S: **Summarize** what the patient has said, calling attention to the salient elements of the discussion and allowing the patient to correct any misunderstandings and add anything that was missed. It is often effective to end a summary with an open-ended statement, such as "I am wondering what you think your next step should be."

During the visit, make sure to ask the patient to state the goal (this helps to confirm agreement) and then write it in the chart, letting the patient know that you will review it together at the next visit.



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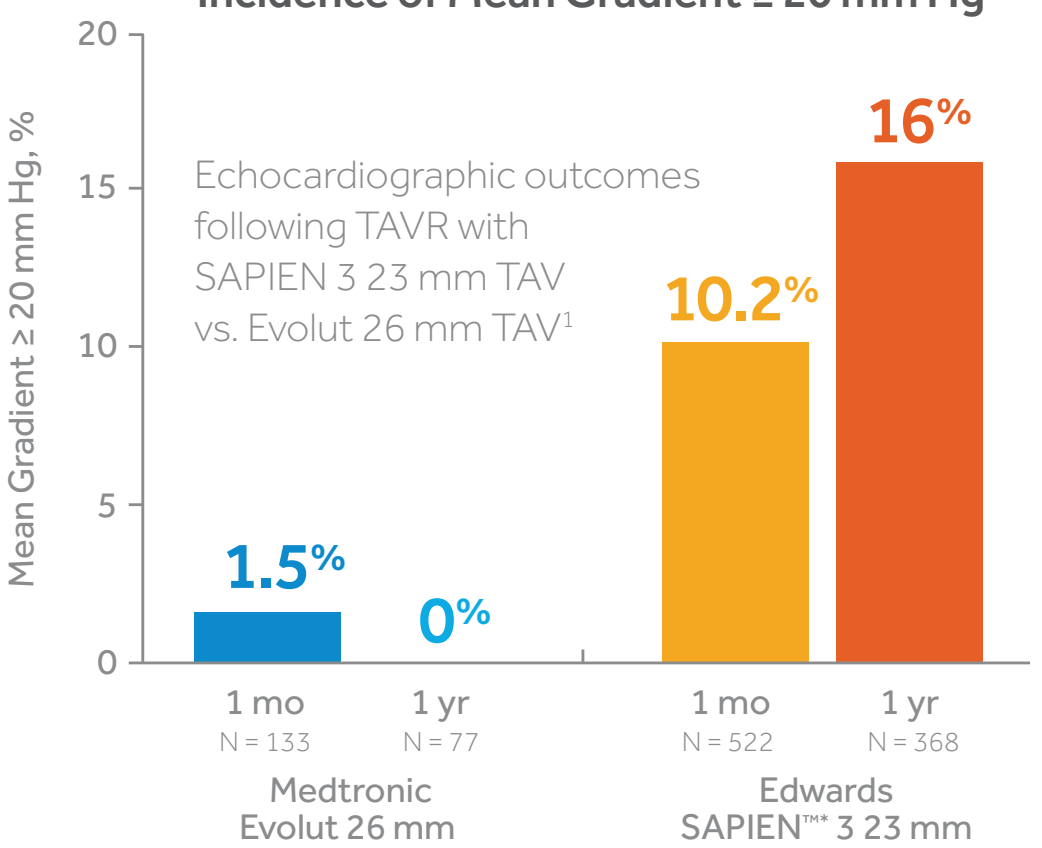
Small Annulus
Big Difference

Incidence of Mean Gradient ≥ 20 mm Hg

Echocardiographic outcomes following TAVR with SAPIEN 3 23 mm TAV vs. Evolut 26 mm TAV[1]



0%

of Evolut 26 mm valves had gradients ≥ 20 mm Hg at 1 year

16%

of SAPIEN 3 23 mm valves had gradients ≥ 20 mm Hg at 1 year

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INDICATIONS The Medtronic CoreValve™ Evolut™ R, CoreValve™ Evolut™ PRO, and Evolut™ PRO+ systems are indicated for relief of aortic stenosis in patients with symptomatic heart disease due to severe native calcific aortic stenosis who are judged by a heart team, including a cardiac surgeon, to be appropriate for the transcatheter heart valve replacement therapy.

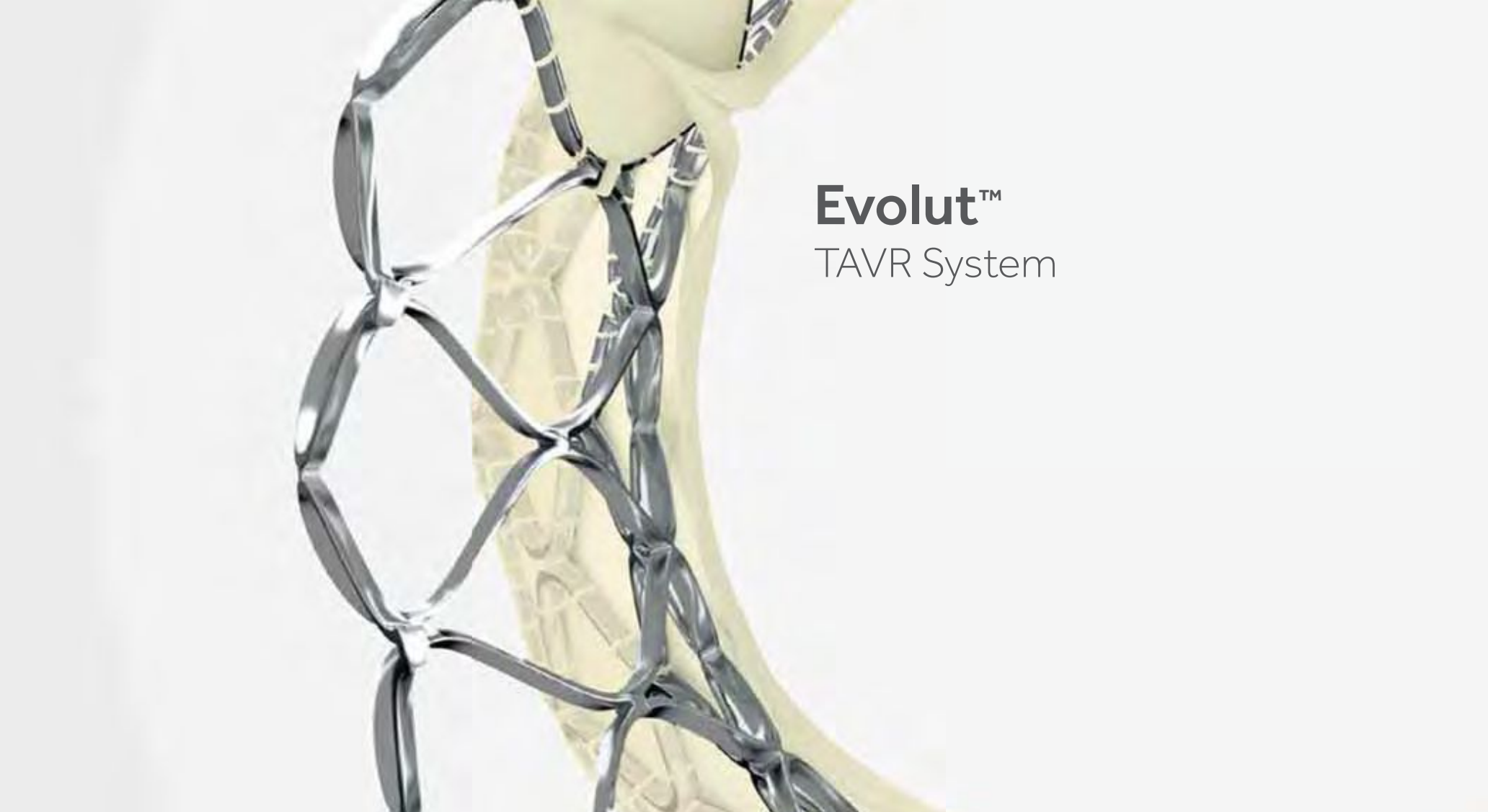
The Medtronic CoreValve Evolut R, CoreValve Evolut PRO, and Evolut PRO+ systems are indicated for use in patients with symptomatic heart disease due to failure (stenosed, insufficient, or combined) of a surgical bioprosthetic aortic valve who are judged by a heart team, including a cardiac surgeon, to be at high or greater risk for open surgical therapy (e.g., STS predicted risk of operative mortality score ≥ 8% or at a ≥ 15% risk of mortality at 30 days).

CONTRAINDICATIONS The CoreValve Evolut R, CoreValve Evolut PRO, and Evolut PRO+ systems are contraindicated in patients who cannot tolerate Nitinol (titanium or nickel), an anticoagulation/antiplatelet regimen, or who have active bacterial endocarditis or other active infections.

WARNINGS *General* Implantation of the CoreValve Evolut R, PRO, and PRO+ systems should be performed only by physicians who have received Medtronic CoreValve Evolut R, PRO, or PRO+ training. This procedure should only be performed where emergency aortic valve surgery can be performed promptly. Mechanical failure of the delivery catheter system and/or accessories may result in patient complications. *Transcatheter aortic valve (bioprosthesis)* Accelerated deterioration due to calcific degeneration of the bioprostheses may occur in: children, adolescents, or young adults; patients with altered calcium metabolism (e.g., chronic renal failure or hyperthyroidism).

PRECAUTIONS *General* Clinical long-term durability has not been established for the bioprosthesis. Evaluate bioprosthesis performance as needed during patient follow-up. The safety and effectiveness of the CoreValve Evolut R, PRO, and PRO+ systems have not been evaluated in the pediatric population. The safety and effectiveness of the bioprosthesis for aortic valve replacement have not been evaluated in the following patient populations: Patients who do not meet the criteria for symptomatic severe native aortic stenosis as defined: (1) symptomatic severe high-gradient aortic stenosis — aortic valve area ≤ 1.0 cm^2 or aortic valve area index ≤ 0.6 cm^2/m^2, a mean aortic valve gradient ≥ 40 mm Hg, or a peak aortic-jet velocity ≥ 4.0 m/s; (2) symptomatic severe low-flow, low-gradient aortic stenosis — aortic valve area ≤ 1.0 cm^2 or aortic valve area index ≤ 0.6 cm^2/m^2, a mean aortic valve gradient < 40 mm Hg, and a peak aortic-jet velocity < 4.0 m/s; with untreated, clinically significant coronary artery disease requiring revascularization; with a preexisting prosthetic heart valve with a rigid support structure in either the mitral or pulmonic position if either the preexisting prosthetic heart valve could affect the implantation or function of the bioprosthesis or the implantation of the bioprosthesis could affect the function of the preexisting prosthetic heart valve; patients with liver failure (Child-Pugh Class C); with cardiogenic shock manifested by low cardiac output, vasopressor dependence, or mechanical hemodynamic support; patients who are pregnant or breastfeeding. The safety and effectiveness of a CoreValve Evolut R, Evolut PRO, or Evolut PRO+ bioprosthesis implanted within a failed preexisting transcatheter bioprosthesis has not been demonstrated. Implanting a CoreValve Evolut R, Evolut PRO, or Evolut PRO+ bioprosthesis in a degenerated surgical bioprosthetic valve (transcatheter aortic valve in surgical aortic valve [TAV-in-SAV]) should be avoided in the following conditions: The degenerated surgical bioprosthetic valve presents with: a significant concomitant paravalvular leak (between the prosthesis and the native annulus), is not securely fixed in the native annulus, or is not structurally intact (e.g., wire form frame fracture); partially detached leaflet that in the aortic position may obstruct a coronary ostium; stent frame with a manufacturer-labeled inner diameter < 17 mm. The safety and effectiveness of the bioprosthesis for aortic valve replacement have not been evaluated in patient populations presenting with the following: Blood dyscrasias as defined as leukopenia (WBC < 1,000 cells/mm^3), thrombocytopenia (platelet count < 50,000 cells/mm^3), history of bleeding diathesis or coagulopathy, or hypercoagulable states; congenital unicuspid valve; mixed aortic valve disease (aortic stenosis and aortic regurgitation with predominant aortic regurgitation [3-4+]); moderate to severe (3-4+) or severe (4+) mitral or severe (4+) tricuspid regurgitation; hypertrophic obstructive cardiomyopathy; new or untreated echocardiographic evidence of intracardiac mass, thrombus, or vegetation; native aortic annulus size < 18 mm or > 30 mm for Evolut R/Evolut PRO+ and < 18 mm or > 26 mm for CoreValve Evolut PRO per the baseline diagnostic imaging or surgical bioprosthetic aortic annulus size < 17 mm or > 30 mm for CoreValve Evolut R/Evolut PRO+ and < 17 mm or > 26 mm for Evolut PRO; transarterial access unable to accommodate an 18 Fr sheath or the 14 Fr equivalent EnVeo InLine™ sheath when using Model ENVEOR-US/ENVPRO-14-US/D-EVPROP2329US or transarterial access unable to accommodate a 20 Fr introducer sheath or the 16 Fr equivalent EnVeo InLine sheath when using Model ENVEOR-N-US/ENVPRO-16-US or transarterial access unable to accommodate a 22 Fr introducer sheath or the 18 Fr equivalent Evolut PRO+ InLine sheath when using Model D-EVPROP34US; prohibitive left ventricular outflow tract calcification; sinus of Valsalva anatomy that would prevent adequate coronary perfusion; significant aortopathy requiring ascending aortic replacement; moderate to severe mitral stenosis; severe ventricular dysfunction with left ventricular ejection fraction (LVEF) < 20%; symptomatic carotid or vertebral artery disease; and severe basal septal hypertrophy with an outflow gradient.

Before Use Exposure to glutaraldehyde may cause irritation of the skin, eyes, nose, and throat. Avoid prolonged or repeated exposure to the vapors. Damage may result from forceful handling of the catheter. Prevent kinking of the catheter when removing it from the packaging. The bioprosthesis size must be appropriate to fit the patient's anatomy. Proper sizing of the devices is the responsibility of the physician. Refer to the Instructions for Use for available sizes. Failure to implant a device within the sizing matrix could lead to adverse effects such as those listed below. Patients must present with transarterial access vessel diameters of ≥ 5 mm when using Model ENVEOR-US/ENVPRO-14-US/D-EVPROP2329US or ≥ 5.5 mm when using Model ENVEOR-N-US/ENVPRO-16-US or ≥ 6 mm when using Model D-EVPROP34US, or patients must present with an ascending



Don't send your patients home with moderate AS

aortic (direct aortic) access site ≥ 60 mm from the basal plane for both systems. Implantation of the bioprosthesis should be avoided in patients with aortic root angulation (angle between plane of aortic valve annulus and horizontal plane/vertebrae) of > 30° for right subclavian/axillary access or > 70° for femoral and left subclavian/axillary access. For subclavian access, patients with a patent left internal mammary artery (LIMA) graft must present with access vessel diameters that are either ≥ 5.5 mm when using Models ENVPRO-14-US/ENVEOR-L-US/D-EVPROP2329US or ≥ 6 mm when using Models ENVPRO-16-US and ENVEOR-N-US or ≥ 6.5 mm when using Model D-EVPROP34US. Use caution when using the subclavian/axillary approach in patients with a patent LIMA graft or patent RIMA graft. For direct aortic access, ensure the access site and trajectory are free of patent RIMA or a preexisting patent RIMA graft. For transfemoral access, use caution in patients who present with multiplanar curvature of the aorta, acute angulation of the aortic arch, an ascending aortic aneurysm, or severe calcification in the aorta and/or vasculature. If ≥ 2 of these factors are present, consider an alternative access route to prevent vascular complications. Limited clinical data are available for transcatheter aortic valve replacement in patients with a congenital bicuspid aortic valve who are deemed to be at low surgical risk. Anatomical characteristics should be considered when using the valve in this population. In addition, patient age should be considered as long-term durability of the valve has not been established.

During Use After the procedure, administer appropriate antibiotic prophylaxis as needed for patients at risk for prosthetic valve infection and endocarditis. After the procedure, administer anticoagulation and/or antiplatelet therapy per physician/clinical judgment. Excessive contrast media may cause renal failure. Prior to the procedure, measure the patient's creatinine level. During the procedure, monitor contrast media usage. Conduct the procedure under fluoroscopy. Fluoroscopic procedures are associated with the risk of radiation damage to the skin, which may be painful, disfiguring, and long-term. The safety and efficacy of a CoreValve Evolut R, Evolut PRO, or Evolut PRO+ bioprosthesis implanted within a transcatheter bioprosthesis have not been demonstrated.

POTENTIAL ADVERSE EVENTS Potential risks associated with the implantation of the CoreValve Evolut R, CoreValve Evolut PRO, or Evolut PRO+ transcatheter aortic valve may include, but are not limited to, the following: ▪ death ▪ myocardial infarction, cardiac arrest, cardiogenic shock, or cardiac tamponade ▪ coronary occlusion, obstruction, or vessel spasm (including acute coronary closure) ▪ cardiovascular injury (including rupture, perforation, tissue erosion, or dissection of vessels, ascending aorta trauma, ventricle, myocardium, or valvular structures that may require intervention) ▪ emergent surgical or transcatheter intervention (e.g., coronary artery bypass, heart valve replacement, valve explant, percutaneous coronary intervention [PCI], balloon valvuloplasty) ▪ prosthetic valve dysfunction (regurgitation or stenosis) due to fracture; bending (out-of-round configuration) of the valve frame; underexpansion of the valve frame; calcification; pannus; leaflet wear, tear, prolapse, or retraction; poor valve coaptation; suture breaks or disruption; leaks; mal-sizing (prosthesis-patient mismatch); malposition (either too high or too low)/malplacement ▪ prosthetic valve migration/embolization ▪ prosthetic valve endocarditis ▪ prosthetic valve thrombosis ▪ delivery catheter system malfunction resulting in the need for additional recrossing of the aortic valve and prolonged procedural time ▪ delivery catheter system component migration/embolization ▪ stroke (ischemic or hemorrhagic), transient ischemic attack (TIA), or other neurological deficits ▪ individual organ (e.g., cardiac, respiratory, renal [including acute kidney failure]) or multi-organ insufficiency or failure ▪ major or minor bleeding that may require transfusion or intervention (including life-threatening or disabling bleeding) ▪ vascular access-related complications (e.g., dissection, perforation, pain, bleeding, hematoma, pseudoaneurysm, irreversible nerve injury, compartment syndrome, arteriovenous fistula, or stenosis) ▪ mitral valve regurgitation or injury ▪ conduction system disturbances (e.g., atrioventricular node block, left bundle-branch block, asystole), which may require a permanent pacemaker ▪ infection (including septicemia) ▪ hypotension or hypertension ▪ hemolysis ▪ peripheral ischemia ▪ General surgical risks applicable to transcatheter aortic valve implantation: ▪ bowel ischemia ▪ abnormal lab values (including electrolyte imbalance) ▪ allergic reaction to antiplatelet agents, contrast medium, or anesthesia ▪ exposure to radiation through fluoroscopy and angiography ▪ permanent disability.

Please reference the CoreValve Evolut R, CoreValve Evolut PRO, and Evolut PRO+ Instructions for Use for more information regarding indications, warnings, precautions, and potential adverse events.

Caution: Federal Law (USA) restricts these devices to the sale by or on the order of a physician.

The commercial name of the Evolut™ R device is Medtronic CoreValve™ Evolut™ R System, the commercial name of the Evolut™ PRO device is Medtronic CoreValve™ Evolut™ PRO System, and the commercial name of the Evolut™ PRO+ device is Medtronic Evolut™ PRO+ System.

[1] Ring ME, et al. Comparison of Echocardiographic Outcomes Following Transcatheter Aortic Valve Replacement with Edwards S3 23 mm versus Medtronic Evolut 26 mm Valves. Poster presented at ACC 2020.

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FEATURE

UNDERSTANDING THE ABIM MOC ASSESSMENT OPTIONS

With the expansion of assessment options for achieving maintenance of certification (MOC) from the American Board of Internal Medicine (ABIM), understanding the difference between the options and choosing the one that works best for you can be challenging. The following table compares the three options available to participating clinicians, including the traditional 10-year exam, the Longitudinal Knowledge Assessment launching in 2022, and the Collaborative Maintenance Pathway (CMP) delivered through ACC's Self-Assessment Programs.

		Traditional, 10-year MOC Exam	Collaborative Maintenance Pathway (delivered through ACC's SAPs)	Longitudinal Knowledge Assessment
	Delivered by	ABIM	ACC and ABIM	ABIM
1	Required Frequency	Every 10 Years	Yearly	Five-year cycle, with 30 questions offered each quarter. Must open at least 500 out of 600 questions offered over five years to meet the LKA Participation Requirement. Start the year your MOC assessment requirement is due.
2	Breadth of Discipline Covered	100% of the field	20% of the field each year. Over 5 years, your entire knowledge base is refreshed, and you start over again in year 6.	100% of the field
3	Number of Questions	180 questions	60 questions per Performance Assessment each year	120 questions offered each year (30 per quarter and you may choose not to open 100 over each five-year cycle)
4	Location	Test center only	At home or workplace. Delivered through ACC's Self-Assessment Programs ACCSAP CathSAP EPSAP HFSAP	Anywhere with an internet connection
5	Available in	• Cardiovascular Disease • Interventional Cardiology • Clinical Cardiac EP • Advanced Heart Failure and Transplant Cardiology	• Cardiovascular Disease • Interventional Cardiology • Clinical Cardiac EP • Advanced Heart Failure and Transplant Cardiology	• Cardiovascular Disease in 2022 • Interventional Cardiology in 2022
6	Learning Materials Included	No	Yes. Educational text, presentations, and hundreds of practice questions are included in each CMP SAP.	No. Physicians can access all the materials they use in practice (except another person). Immediate feedback is provided with every question. Regular score reports are provided beginning in the second year of participation.
7	Open Book	Yes, through access to UpToDate®	Yes, through the SAP educational material, or through any resource except another person	Yes, through any resource except another person
8	Immediate Results	No. Results received within three months of administration.	Yes, 85% of participants will receive immediate feedback about their pass/fail status upon submitting the assessment. All participants will receive a detailed Score Report two weeks after the assessment window closes.	No. The determination on meeting the performance standard is made at the end of the five-year cycle. During this cycle, feedback is provided on your progress, including relative to the passing score.
9	Availability	Two times a year	Two one-week windows each year	New questions delivered quarterly
10	Points	20 MOC points for every assessment attempt	Each CMP SAP offers 60 to 160 CME and MOC points per year	0.2 MOC points for every correct answer 20 MOC points for every 100 questions answered correctly
11	Maximum amount of time required to participate	Study time varies for each participant One full day of testing **Time estimates based on approximately two minutes per question*	Nine hours per year (seven hours of learning, two hours to complete a performance assessement) **Time estimates based on two minutes per question*	Study time varies for each participant Eight hours per year to complete the quarterly questions *(30 questions x 4 minutes per question each quarter = 2 hours per quarter)*
12	When can you first attempt/ take?	In Year 6	To gain experience with the program ***without the stress of achieving a passing score,*** start early (before the year your MOC assessment is due)	Start the year your MOC assessment is due
13	What happens if you don't pass?	If you don't pass in the year your assessment is due, your certification is maintained if you are meeting your other MOC requirements. If you don't pass in the year your assessment is due, you won't lose certification as long as you are meeting your other MOC requirements. You can take the traditional, 10-year MOC exam in the following year, and if you pass and all other MOC requirements are met you will remain certified and your next assessment will be due in 10 years.		

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Learn more about the CMP and enroll at *ACC.org/CMP*.
Visit the ABIM website for more on the other two assessment options. ACC members currently participating in CathSAP, EP SAP and HF SAP should note the last CMP Performance Assessment Period for 2021 will take place Dec. 8-14.

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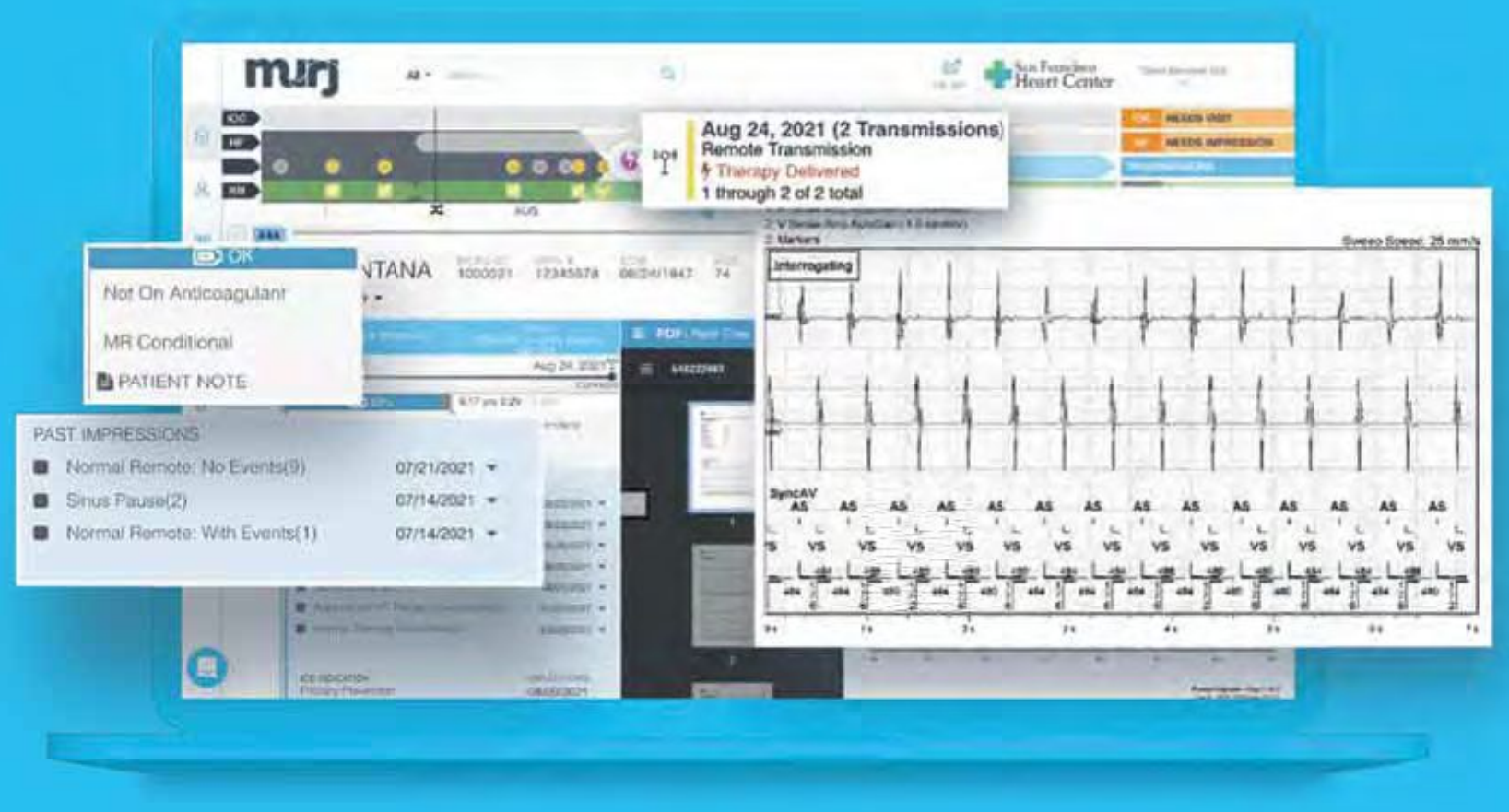

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FEATURE

Health Policy Implications to Reduce **Severe Maternal Morbidity and Mortality**

Maternal mortality is rising in the U.S. In fact, with a concerning ratio of 17.4 deaths per 100,000 live births, based on 2020 data from the Centers for Disease Control and Prevention, the U.S. has the highest rate of maternal mortality among countries with comparably high sociodemographics.[1,2]

Cardiovascular disease and cerebrovascular disease – the leading causes of maternal death, combined account for more than 33% of deaths. Notably, heart disease and stroke were the leading cause of pregnancy-related deaths from 2011-2017 and in 2020 this continues to be the case. Most importantly, these deaths are largely preventable, with some 70% of the maternal deaths related to cardiovascular disease preventable with risk factor modification.[1]

Disparities in Maternal Outcomes

Key factors that contribute to cardiovascular-driven maternal morbidity and mortality include high rates of unplanned pregnancy, inconsistent access to care and health insurance, rising rates of chronic diseases such as obesity, hypertension and diabetes, as well as advanced maternal age in women of child-bearing age.[1,2]

Striking disparities exist in maternal outcomes in the U.S. A strong body of literature reveals that racial/ethnic and rural/urban disparities contribute to adverse cardiovascular outcomes in pregnancy and beyond, often mitigated by adverse sociodemographic factors.

Black women, compared with White women, have a substantially higher risk for: [2]

- Mortality (odds ratio [OR], 1.45; 95% confidence interval [CI], 1.21-1.73)
- Myocardial infarction (OR, 1.23; 95% CI, 1.06-1.42)
- Stroke (OR, 1.57; 95% CI, 1.41-1.74)
- Pulmonary embolism (OR, 1.42; 95% CI, 1.30-1.56)
- Peripartum cardiomyopathy (OR, 1.71; 95% CI, 1.66-1.76).

Moreover, insurance coverage, or the lack of it, has an impact on maternal outcomes. Among Black, Indigenous (Native American or Alaskan Native) and rural women, compared with White women and urban women, there's a high rate of births that are funded by Medicaid. This is significant because in states that do not have Medicaid expansion, health insurance coverage ends 60 days postpartum, despite data showing that cardiovascular disease-related deaths contribute to the largest cause of pregnancy-related deaths from Days 42 to 365 postpartum.[1,2]

Higher rates of comorbidities are present in women who live in rural areas and/or are from racial/ethnic minority groups, increasing their risk for adverse cardiovascular outcomes.[1,2] These comorbidities include diabetes, hypertension, hyperlipidemia, obesity and smoking.

There are also significant disparities in adverse pregnancy outcomes (APOs), which include hypertensive disorders of pregnancy (including preeclampsia and gestational hypertension), preterm delivery, gestational diabetes, small-for-gestational-age delivery, placental abruption and pregnancy loss.[1,2] A growing body of evidence shows these APOs are associated with an increased risk of subsequent cardiovascular disease.[1,2]

The relative risk for APOs, based on a recent analysis of data from the National Center for Health Statistics, is higher in several racial/ethnic groups compared with non-Hispanic White women: 1.15 (95% CI, 1.13-1.18) for Hispanic women, 1.78 (95% CI, 1.74-1.82) for Asian/Pacific Islander women and 0.97 (95% CI, 0.94-0.99) for non-Hispanic Black women.[1]

Gestational diabetes rates were the highest in Asian Indian participants in a recent study reported by Shah, et al, with a relative risk of 2.24 (95% CI, 2.15-2.33).[3]

Studies have also documented higher rates of preeclampsia among non-Hispanic Black women, and disproportionately higher rates of death from complications of preeclampsia compared with their non-Hispanic White counterparts.[1]

Severe Maternal Morbidity and Early Warning Triggers

Another important maternal outcome to recognize is severe maternal morbidity (SMM), which remains poorly defined, but encompasses unexpected outcomes of labor and delivery. These include significant cardiovascular consequence such as myocardial infarction, aneurysm, cardiac arrest, heart failure and cerebrovascular disorders.[1] Like maternal mortality, SMM is preventable and several in-hospital measures and safety initiatives can help reduce it.

SMM is much more common than mortality. For every maternal death, 100 women suffer a severe obstetric morbidity, a life-threatening diagnosis or undergo a lifesaving procedure during their delivery hospitalization.[1] SMM affects >60,000 women annually in the U.S., and this number has been on the rise over the last few decades with similar rural and racial disparities.[1]

In fact, Black women have the highest rates for 22 of 25 indicators of severe morbidity from SMM.[1] Data have consistently shown that hospitals which perform higher numbers of deliveries of Black or Hispanic infants (>50% or hospitals with highest quartile of proportions of minorities) disproportionately have higher risk adjusted SMM rates compared with hospitals primarily serving lower rates of Black or Hispanic patients. Studies have also consistently found higher pregnancy-related mortality risks in Black women, even when controlling for factors such as insurance coverage, marital status and medical conditions.[1]

There is a profound disadvantage identified among Indigenous women residing in rural counties, with two-thirds living in counties with median incomes in the bottom national income quartile. Indigenous women residing in rural counties also have the greatest risk for preexisting, chronic conditions complicating childbirth, including diabetes and substance use disorders.

SDOH and Adverse Pregnancy Outcomes

The World Health Organization (WHO) defines social determinants of health (SDOH) as "conditions in which people are born, grow, work, live, and age." This framework has been used extensively in health care disparities research and has increasingly been recognized and tied to APOs and maternal inequities.[1] This framework includes factors such as economic stability and socioeconomic status, neighborhood and physical environment, transportation, education, health literacy, food security, racial discrimination, psychosocial stressors and insurance coverage.[1]

Importantly, SDOH such as socioeconomic disadvantages, poor health literacy, transportation barriers, lack of access to adequate health care, food insecurity and psychosocial stressors have cascading effects on APOs and downstream cardiovascular health. These SDOH are also deeply intertwined with and are compounded by existing racial and rural disparities.

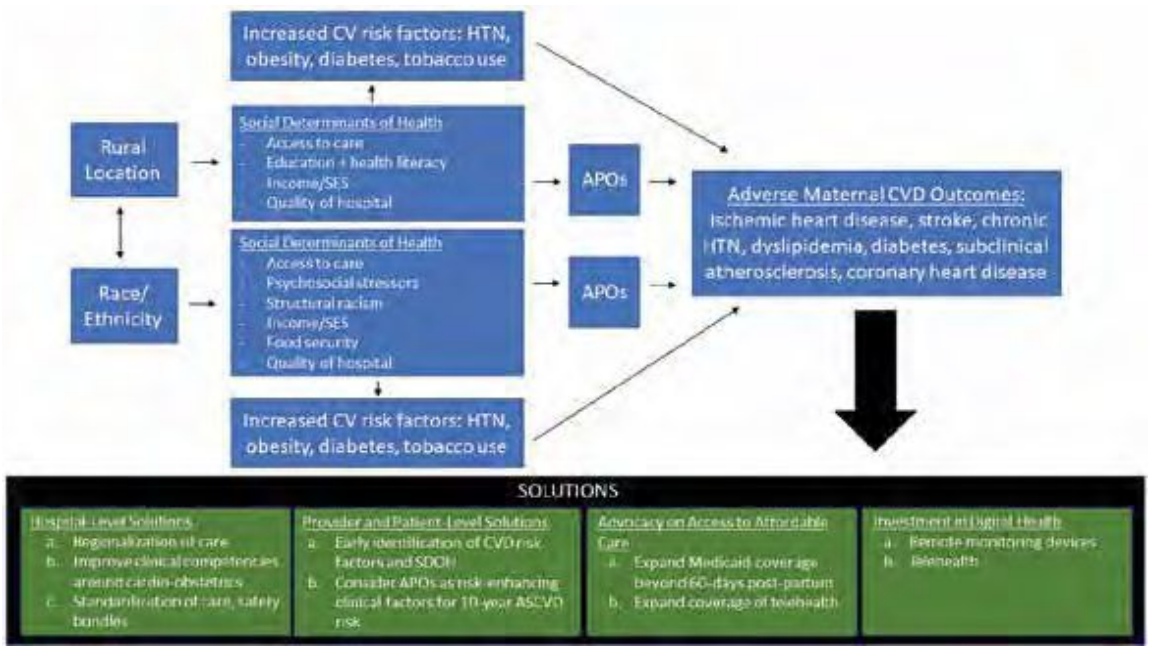
Health Policy Implications to Bridge the Gap and Reduce Adverse Outcomes

A recent policy statement on maternal health from the American Heart Association provides strategies to reduce overall deaths and address racial disparities in maternal health through a three-pronged approach focused on patients, health care providers and care systems. This approach includes:

- **Addressing disparities and inequities** by educating providers, improving reporting of maternal outcomes, expanding Medicaid funding in states where it doesn't exist and increasing public awareness about activities to reduce heart disease (such as smoking cessation). Teaching health equity curricula in medical school and addressing SDOH by developing EMR-based metrics on how to report SDOH.
- **Increasing multidisciplinary care with early detection, prompt management and close and extended follow-up.** Cardio-obstetric programs are much needed for obstetricians, gynecologists and maternal-fetal medicine colleagues to work closely with adult cardiologists, adult congenital heart disease cardiologists, advanced heart failure specialists, patient navigators and coordinators, advanced nursing practitioners, critical care and obstetric anesthesia, and genetic counselors to provide this multidisciplinary care.
- **Modernizing maternal health care delivery** by informing women of preconception counseling, expanding postpartum care for Medicaid participants to the first year after delivery and transforming provider payment to prioritize high quality, low cost and eliminate unnecessary services. This would support Medicaid expansion in all 50 states and support legislation extending Medicaid from 60 days postpartum to a full year. Elevate guidelines for continued monitoring for latent development of hypertension, cardiovascular disease and stroke in clinical practice. It also supports access to postpartum care that assesses physical, social and psychological well-being. Finally, these guidelines improve health literacy of the patients and their families to identify early warning tools and promote preventive care through Life's Simple 7 metrics.
- **Updating technology and systems** by modernizing the public health care infrastructure in under-resourced communities and closing the gaps between health care in urban and rural areas. Improving digital health and remote monitoring.
- **Quality reporting of maternal outcomes and health metrics.** The policy statement supports robust individual state maternal mortality review committees and standardizes quality measures for maternal morbidity and mortality.

While federal legislation is extremely important for large-scale policy, state-level policy will govern the health care coverage for prepregnancy and postpartum care in nearly half of all women who become pregnant. While historically the care of the majority of cardiac patients has been funded by the Centers for Medicare and Medicaid Services and ACC advocacy efforts have been targeted at the federal level, our efforts at the state level will need to be redoubled now that cardiac care is increasingly required in pregnant/postpartum women and ongoing telehealth coverage will help advance such care. We urge cardiologists to partner with their state societies and work together to improve maternal health in their state.

Impact of Disparities, SDOH on Maternal CV Outcomes and Health Policy Solutions



Two Federal Bills Moving Maternal Health Forward

Black Maternal Health Momnibus Act of 2021. This Act builds on existing legislation to comprehensively address every dimension of the maternal health crisis in America. **Scan this QR code to learn more and support this bill.**

Mothers and Offspring Mortality and Morbidity Awareness Act. The MOMMA's Act will improve data collection, disseminate information on effective interventions and expand access to health care and social services for postpartum women. In addition, the bill would expand coverage for postpartum care for up to one year under Medicaid and CHIP. This bill is supported by the American Medical Association. **Scan this QR code to learn more and support this bill.**

This article was authored by **Lochan Shah, MD,** internal medicine resident at Johns Hopkins University School of Medicine, Baltimore, MD; **Laxmi S. Mehta, MD, FACC,** vice chair of wellness, Department of Internal Medicine, section director of Preventative Cardiology and Women's Cardiovascular Health, director of lipid clinics, Sarah Ross Soter Endowed Chair in Women's Cardiovascular Health, and professor of medicine at The Ohio State University in Columbus; **Colleen M. Harrington, MD, FACC,** assistant professor of medicine, associate program director of the cardiology fellowship program, and co-director of the Women's Cardiovascular and Pregnancy Clinic at the University of Massachusetts School of Medicine in Worcester, and adjunct assistant professor of medicine at Johns Hopkins School of Medicine; **Malissa J. Wood, MD, FACC,** associate professor of medicine at Harvard Medical School and co-director, Corrigan Women's Heart Health Program, Massachusetts General Hospital in Boston; and **Garima Sharma, MD, FACC,** assistant professor of medicine, associate vice chair for Women's Careers in Academic Medicine, director of cardio-obstetrics, and associate director of preventive cardiology-education at Johns Hopkins University School of Medicine.

Mehta is chair of ACC's Board of Governors Wellness Work Group. Harrington is governor-elect of the Massachusetts ACC Chapter. Wood is a Trustee of the ACC, chair-elect of the ACC Board of Governors and governor of the Massachusetts ACC Chapter. Sharma is governor of the ACC Maryland Chapter.

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3. Shah NS, Wang MC, Freaney PM, et al. *JAMA* 2021;326:660-9.

COVID-19 Vaccine Hesitancy Among Pregnant Women: **What Can OB/GYNs and Cardiologists Do Together?**

As new data continue to evolve on the severity of COVID-19 infection in pregnant women and its effects on adverse pregnancy outcomes, cardiologist and obstetricians have a renewed responsibility towards addressing these concerns along with other cardiovascular and obstetric questions. In our communities across the country, there's much hesitancy about this vaccine, and it's no different among women who are pregnant.

In fact, obstetric consultants and practitioners can attest to the self-discontinuation of needed and chronically taken cardiovascular, rheumatologic and immunosuppressive medications at conceptus by newly pregnant patients. Thus, this "medication hesitancy" has evolved into the vaccine hesitancy we see today among pregnant women.

Pregnant women often have concerns about the impact of the vaccine, as well as other medications, and many of these concerns come from myths and misunderstanding. However, it is important to address the concerns of pregnant women about the effects of COVID-19 with an intent for an informed evidence-based decision.

Owing to the paucity of clinical trials involving pregnant women, clinicians nearly always must rely on registry or retrospective observational data regarding the use of medications, therapies and even vaccines. The COVID-19 vaccine is no different.

A study published last month in the *American Journal of Obstetrics and Gynecology* showed that COVID-19 infection during pregnancy, compared with no infection, is strongly associated with preeclampsia (8.1% vs. 4.4%; relative risk, 1.8; 95% confidence interval [CI], 1.32-2.61), especially among nulliparous women (risk ratio, 1.89; 95% CI, 1.17-3.05).[1] Preeclampsia is a well-recognized cardiovascular risk factor in women and should be part of prepregnancy counseling. Additionally, pregnant women and those with existing cardiovascular conditions such as diabetes, obesity, chronic hypertension, cardiomyopathy, etc., are at increased risk of severe illness from COVID-19 compared with nonpregnant women.

Additionally, intensive care unit (ICU) admissions in pregnant women with COVID-19 are higher. Data from a recent study published in *JAMA Network Open* showed that compared with nonpregnant women, pregnant women were more frequently admitted to an ICU (10.5 vs. 3.9 per 1,000 cases; aRR, 3.0; 95% CI, 2.6-3.4), received invasive ventilation (2.9 vs. 1.1 per 1,000 cases; aRR, 2.9; 95% CI, 2.2-3.8) and received mechanical circulatory support (0.7 vs. 0.3 per 1,000 cases; aRR, 2.4; 95% CI, 1.5-4.0). The data reflect a 70% increased risk for death associated with pregnancy in this population (aRR, 1.7; 95% CI, 1.2-2.4). Irrespective of pregnancy status, ICU admissions, receipt of invasive ventilation and death occurred more often among women aged 35-44 years and was higher in Black and Hispanic women.[2]

The American College of Obstetricians and Gynecologists (ACOG), the Society for Maternal-Fetal Medicine (SMFM), and the U.S. Centers for Disease Control and Prevention recommend that pregnant and breastfeeding women get a COVID-19 vaccine.[3,4] It is important that as obstetric consultants and providers we address the uncertainty and hesitancy for the COVID-19 vaccine in our pregnant patients. ACOG and SMFM have provided guidance to assist in these conversations.[5-7] In doing this, we may also address concerns of other "medication hesitancy" that has troubled this specialized population for decades. The hope is this susceptible and medically vulnerable population is able to make an informed decision for themselves and their families.

References available with the online version of this article at ACC.org/Cardiology.

Scan the QR code for the clinician's conversation guide on COVID-19 vaccine and pregnancy.


This article was authored by **Garima Sharma, MD, FACC,** and **Arthur J. Vaught, MD,** director of Labor and Delivery at Johns Hopkins Hospital and assistant professor of gynecology and obstetrics at Johns Hopkins University School of Medicine.

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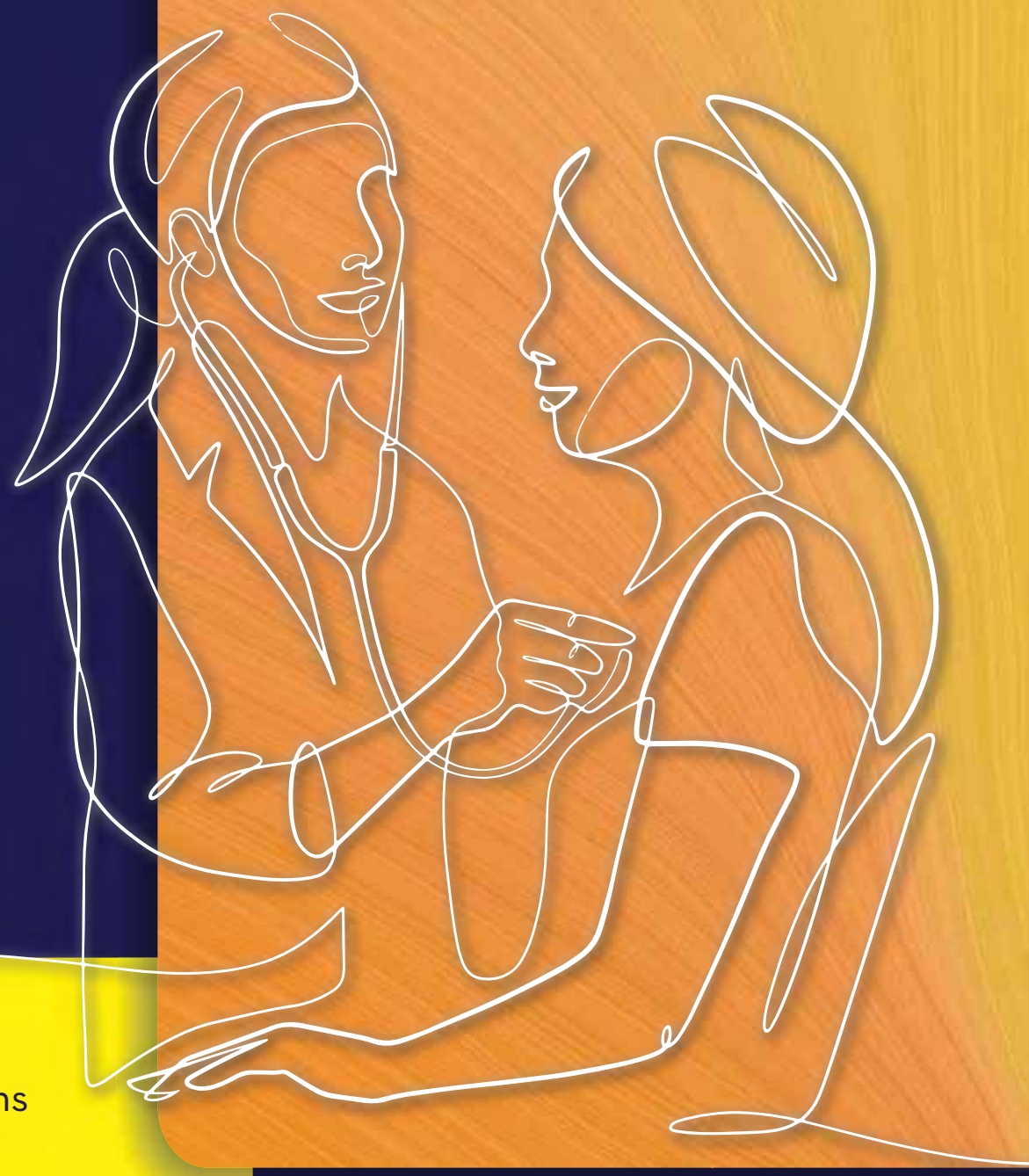

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Remote Monitoring in CHF: **Staying #Healthy@Home**

The optimal treatment and management of congestive heart failure (HF) is an area in cardiology that continues to be elusive. The more we learn, it seems the less we know. After decades of prescribing relatively static HF regimens with a beta-blocker and renin-angiotensin-aldosterone antagonist backbone, the past decade has witnessed an explosion of trials demonstrating the incremental benefit of novel pharmacotherapeutics. We have welcomed several new tools to the pharmacologic armamentarium that have now become integral to our practice: the I_f channel blocker (ivabradine), angiotensin-receptor neprilysin inhibitors (ARNIs, like valsartan/sacubitril), SGLT2 inhibitors (dapagliflozin, empagliflozin, etc.), and soluble guanylate cyclase (sGC) stimulators (vericiguat).

Despite these advances and the growing number of pharmacological options, treating patients with HF remains extremely challenging and burdensome to all parties. Morbidity and mortality remain a major burden to patients, caregivers and national health care systems.[1] The toll is substantial, with a 10% mortality rate at 30 days after hospital discharge,[2] 50% rate of readmission for HF at six months,[3,4] and the risk of mortality increases with each hospitalization.[5] There is a remarkable one-year mortality rate of approximately 20% in patients who have been hospitalized for HF.[6] In sheer dollar terms, the cost of treating HF is staggering, at an estimated $30.7 billion in 2012, including medications, health care services and missed days of work.[7] By 2030, it's projected the total cost of HF will hit $70 billion.

Key to the management of HF are frequent clinical assessments of evolving symptoms and changes on physical examination as well as titration of guideline-directed medical therapy, which are essential to mitigate progression and decompensation of HF. However, the COVID-19 public health emergency, with stay-at-home orders and physical distancing, has made this standard approach challenging.

This challenge, though, has led to new opportunities as health care systems have rapidly deployed and refined a new model of care: the virtual visit. These virtual visits have increased the reliance on remote monitoring which had not been in widespread use previously.

Benefits of Remote Monitoring

Remote monitoring of intracardiac and pulmonary artery pressures can provide clinicians with access to actionable pathophysiological information, and help improve the serial decision-making process necessary to prevent HF hospitalizations and improve other clinical outcomes.[8] This is largely because studies have demonstrated that increases in cardiac filling pressures can often be detected several weeks before patients experience symptoms of acute decompensated HF that require hospitalization, providing clinicians with a therapeutic window of time for effective intervention.[9]

Ms. Buck and Ms. Davis at the KDMC HF Clinic.

Recent technological advances have allowed increasingly sophisticated attempts to remotely monitor and manage the HF syndrome. These advances range from simple, telephone-call based, remote assessment by a HF nurse specialist with the aid of a weight scale and blood pressure cuff to standalone home-based systems to implanted devices (such as cardiac resynchronization therapy and implantable cardiopulmonary sensors) to wearable technologies that have opened up a world of possibilities.

Collecting data remotely has not been difficult. The challenges are integrating such potentially continuous data streams into systems of care and then to convert more data into better decision-making that improves the outcome or experience of care.

As the director of a HF program in rural America, I can attest to the struggles that clinicians in a rural, geographically sprawling catchment area of more than 100 miles in all directions encounter when treating patients with complex, multidisciplinary problems such as HF. Uniquely, in my geographic area, there is also a paucity of internet and cellular telephone access, further adding to the challenge of utilizing remote monitoring strategies that would serve our patients.

Given the struggles we face with this patient population and the difficulty of seeing all patients in the office, our program has opted to pursue a strategy of remote monitoring utilizing the CardioMEMS implantable pulmonary artery sensor, the only one approved by the U.S. Food and Drug Administration.

Since our first implant of a CardioMEMS device at King's Daughters Medical Center (KDMC) in 2016, we have widely expanded its use to help manage patients who have had repeated readmissions for HF with great success. KDMC now monitors more than 125 patients with the CardioMEMS device.

Recently I visited with a provider and a patient on the front line in the fight against HF. **Barbara Davis, BSN, RN**, is the lead nurse of the KDMC HF Clinic and she is responsible for managing our CardioMEMS patients. **Janet Bliss Buck** recently celebrated her 85th birthday and spoke with us by phone from her home in rural Kentucky. We talked about living with and treating HF and their experiences with the CardioMEMS device.

Krishnan: What are some of the challenges our patients face living in a rural area compared to an urban area?

Davis: Although I grew up in Appalachia, because I lived in Houston, TX, for several years I

have an understanding of both lifestyles. One of the most unique aspects of living in Appalachia is the large extended family units that are tight knit and able to provide support to most patients. However, living in a remote area means our patients often live more than an hour away from the closest health center. There's also a significant socioeconomic bridge to get the things they need. This area has had a real downturn in the economy, which started well before the pandemic. Many of our younger patients have lost their jobs in the steel mills and railroad yards and the shift to cleaner fuel has led to a decline in Ashland Oil. Then we also lost the only other hospital system in the neighboring county which has also put our resources under more strain. The lack of medical literacy and the lack of phone/internet access compounds these challenges.

We have a tremendous number of patients with whom we'd like to have telehealth visits, but they do not own a cell phone and they do not have cellular or internet service that is sufficient for a video visit. We also have some patients who have difficulty transmitting CardioMEMS readings to our clinic through landlines.

Krishnan: From a provider's perspective, how does living in a rural area compare to an urban area?

Davis: If the patient does not have financial means or transportation, the patient is unable to do the necessary follow-up which then makes the visit less useful. We do everything in our power to help patients get remote assistance. One of our clinic nurses, just last week, drove to a gas station near a patient's home to obtain the patent's signature on the paperwork for the patient assistance program. Even if we're able to obtain a reduction in the patient's co-pay, say from $500/month to $40/month, this still may not be affordable and may mean the patient is not able to afford their other medications because many are on fixed incomes.

Krishnan: How has your approach to remote monitoring changed during your career?

Davis: When I first started my nursing career in 2005 remote monitoring and telehealth were not part of the vernacular.

However, within a few years we started using a program called TeleHealth Monitoring System that was placed in the home and consisted of a weight scale, blood pressure monitor and a pulse oximetry machine. This was hooked up to a landline and the information came into a secure website. I would even check this on weekends. If patients had a gain in weight >3 lbs, I'd call them to assess symptoms. This was our approach to keep patients out of the hospital. We used this system for two to three years and it worked perfectly for patients who were adherent in sending information to the clinic, but it was worthless for patients who did not engage with the system.

We paid dearly for installing each system and when there was a downturn in our local economy resulting in widespread layoffs, the TeleHealth system was one of the first casualties as it was deemed to be cost prohibitive. After this, we kept a list of patients who we touched base with frequently and did 1:1 phone visits with patients who did not have much family support. And we did the same for patients who were frequent visitors to the emergency department. We also started HF support groups which were well attended by patients and families.

Now we are monitoring patients using the CardioMEMS device and the program continues to grow.

Krishnan: Have you seen success with the CardioMEMS program?

Davis: Yes. We have patients who had multiple admissions pre-implant who have since been able to stay out of the hospital. When we call patients with concerns about increased pressure based on the remote monitoring, they are totally amazed because then they recognize they had some increase in weight. Overall, we have seen a reduction in readmission in patients who have been implanted with the device.

Krishnan: Ms. Buck, please tell me a little bit about your HF journey. When and how were you diagnosed?

Buck: I was in the hospital a few years ago and I had two heart caths. They both turned out okay, but then I had fluid that was gathering and my feet were swelling so bad. I have stage 4 kidney disease and my kidney doctor has had me on Lasix for years, but still I had swelling so bad that I was referred to the congestive heart failure clinic and that's when I found out I had HF.

Krishnan: What has been your experience with CardioMEMS?

Buck: It was implanted on the day after Christmas in 2017. I was the seventh patient at King's Daughters to get one. At first, I didn't understand what it was or where it was placed. Then I spoke with the technician who helped me set it up and explained it to me and it makes a lot of sense. I do the readings every day, by just laying on a pillow that talks to me and tells me not to move. It takes just a few minutes and the information goes to the HF clinic and I think it goes to my kidney doctor's office too.

This monitoring is helpful because it lets me know if I am having too much fluid and gives me an early warning sign that I need to change my diet. It also allows the HF clinic to keep in touch with me and that makes me feel secure. Before I got this, I did not keep up with my weight or blood pressure. Doctors were just kind of guessing about how much fluid I took in. Plus, because I live almost 45 minutes away from the HF clinic it is difficult for me to get there.

Krishnan: What is the hardest thing about having heart failure?

Buck: Oh, it's the fluid, I think. Being limited on how much fluid I can have is very difficult especially during the hot Kentucky summer. I'm hoping this monitoring is keeping me on track and that I won't have a heart attack or a stroke.

References are available with the online version of this article at ACC.org/Cardiology.

This article was authored by **Sandeep Krishnan, MD, RPVI, FACC**, an interventional and structural cardiologist at the King's Daughters Medical Center in Ashland, KY.

Nkechi Ijioma, MD, FACC

Left Main Revascularization: Primer For Early Career Cardiologists

A 60-year-old man unvaccinated for COVID-19 presents to an emergency department of a community hospital with severe chest pain and shortness of breath lasting one to two hours. His medical history is significant for hypertension, diabetes, hyperlipidemia and active COVID-19 (on treatment with casirivimab/imdevimab). He is tachycardiac (heart rate 138 bpm), tachypneic (respiratory rate 37 breaths/minute) and slightly hypertensive (blood pressure 139/100 mm Hg). Chest X-ray shows diffuse bilateral airspace disease.

The patient's electrocardiogram shows ST elevation in leads V2 -V6 concerning for an acute anterior STEMI. The cardiac cath lab is activated. Aspirin 324 mg, clopidogrel 600 mg and IV heparin 7000 Unit bolus are administered and bilevel positive airway pressure is initiated for respiratory support. Diagnostic coronary angiography reveals an 80% ostial left main (LM) lesion stenosis, multiple stenoses in the left anterior descending artery (LAD) with TIMI 2 flow distally (80% proximal LAD, 99% mid LAD and 70% distal LAD), an anomalous left circumflex (LCx) which arose from the right cusp and multiple obstructive lesions in the right coronary artery (**Figure 1**).

Question: What is your revascularization strategy?

a. PCI to the infarct-related artery (IRA) only.

b. Immediate PCI to the IRA and refer for LM artery surgical revascularization.

c. Immediate PCI to the LAD and LM vessel.

d. Multivessel PCI to the LAD, LM, LCx and right coronary artery.

e. Insert a mechanical circulatory support device and refer for surgical revascularization.

Case Review: Clinical Setting

Primary PCI For IRA vs. Complete Revascularization

In acute STEMI, primary PCI of the IRA is recommended (Class I, ESC 2017 guideline).[1] In STEMI patients with multivessel coronary artery disease (CAD), non-IRA revascularization should be considered prior to hospital discharge (Class IIa, Level of Evidence A, ESC 2018 guideline).[2]

Emergency surgical revascularization can be considered for STEMI patients with IRA anatomy not suitable for PCI, ongoing ischemia and a large myocardial area at risk (Class IIa, ESC 2018 guideline). In patients for whom surgical revascularization is intended, if a large myocardium is at risk or there is hemodynamic instability, the guideline allows for proceeding with surgery after discontinuing dual antiplatelet therapy (DAPT) without the usual waiting period for full recovery of platelet function (ESC 2017 guideline).

Cardiogenic Shock

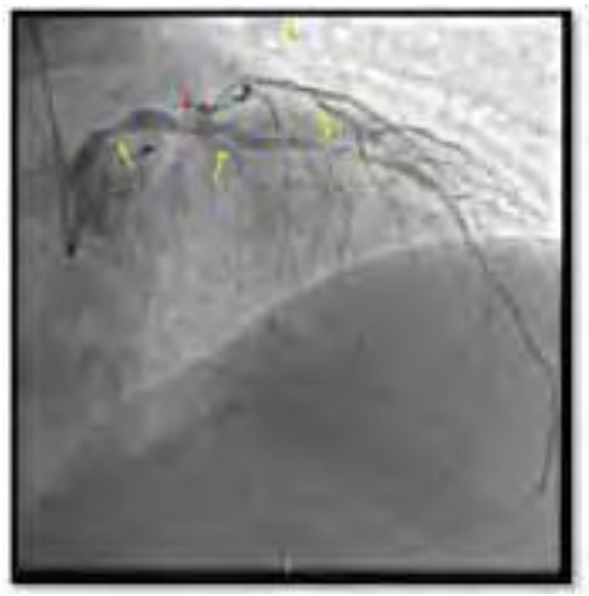
A 2021 American Heart Association scientific statement recommends PCI of the IRA for acute MI complicated by cardiogenic shock regardless of time delay.[3] The scientific statement further recommends that for most patients, PCI should be limited to the culprit lesion with possible staged revascularization of the nonculprit lesions. This approach is supported by the ESC 2018 guideline, which recommends against routine revascularization of the non-IRA lesion during STEMI PCI complicated by cardiogenic shock (Class III).

The AHA scientific statement also supports a hybrid approach of culprit lesion PCI (with or without stent placement) followed by staged surgical revascularization for patients with acute MI complicated by cardiogenic shock and multivessel CAD. Emergency surgical revascularization is recommended for patients with cardiogenic shock if the coronary anatomy is not suitable for PCI (Class I, ESC 2018 guideline).

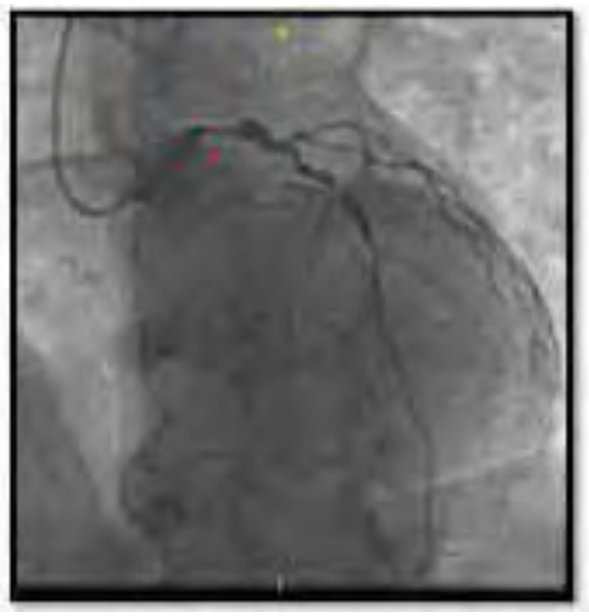
COVID-19 Positive Patients

Primary PCI as the main reperfusion strategy for STEMI has been recommended by several cardiovascular societies. ACC, SCAI and the American College of Emergency Physicians recommend PCI as the main/preferred reperfusion strategy for STEMI patients during the COVID-19 pandemic (**Figure 2**).[4] Primary PCI as first-line therapy for STEMI is also recommended by the European Association of Percutaneous

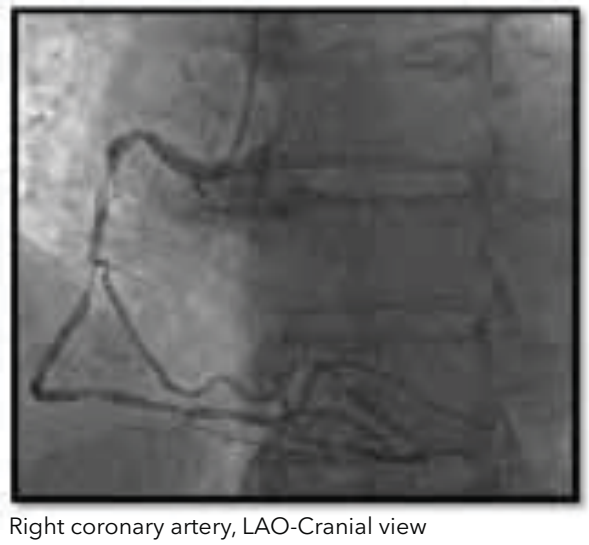
Figure 1 Coronary Artery Lesions



RAO-Cranial view



LAO-Cranial view



Right coronary artery, LAO-Cranial view

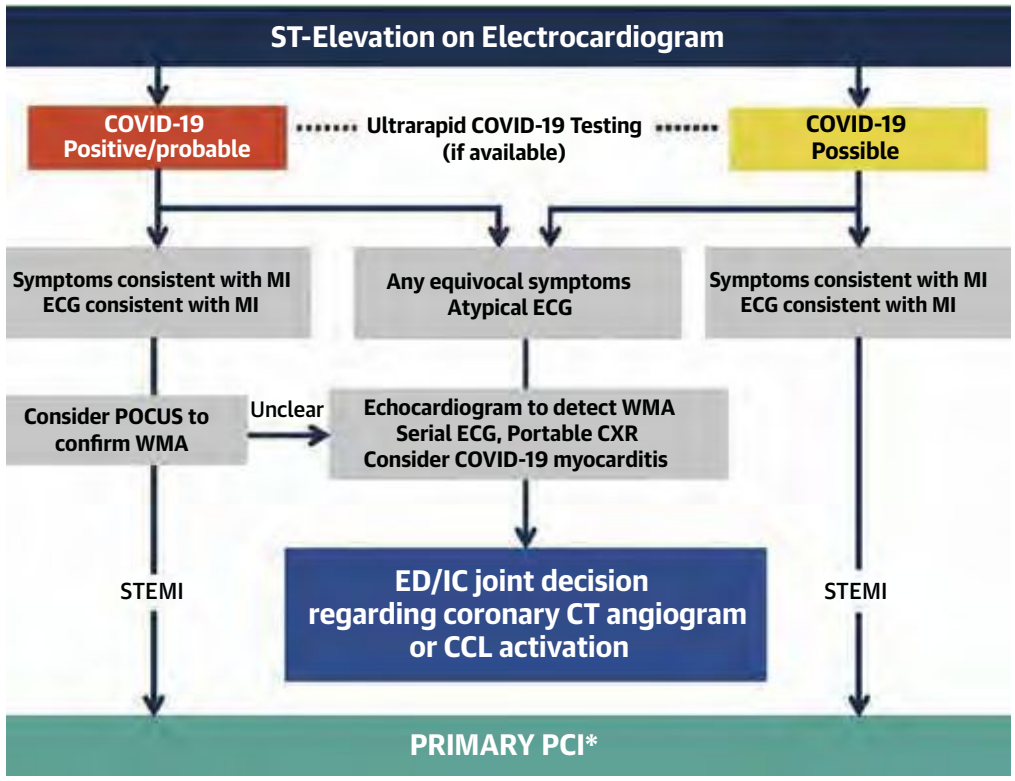
Cardiovascular Intervention (EAPCI) if it can be performed within 120 minutes from symptom onset **(Figure 3)**.[5] The North American Society Leadership also recommends primary PCI for most STEMI patients and selective pharmacoinvasive therapy in accordance with regional practice.[6,7]

Regarding the location for the management of STEMI patients with cardiogenic shock who are positive for COVID-19, the EAPCI recommends expert centers which can provide different options for mechanical circulatory support.

For COVID-19-positive patients experiencing a STEMI with mechanical complications, an intra-aortic balloon pump (IABP) is an option if other mechanical circulatory support devices are not available. Veno-arterial extracorporeal membrane oxygenation (VA ECMO) is the recommended device for COVID-19 patients with hemodynamic and respiratory failure. Impella or IABP can be used for management of left ventricular overdistension in VA ECMO patients.

Initial data from the North American COVID-19 Myocardial Infarction Registry reveals that primary PCI is the predominant reperfusion strategy for COVID-19-positive STEMI patients.[8] It will be interesting and valuable to see the long-term patient outcomes data from this registry.

Figure 2 STEMI Treatment Algorithm Leading to Primary PCI Center



In COVID-19 positive or probable patients, with classic clinical symptoms and ECG findings, a point of care ultrasound (POCUS) evaluation of cardiac function to assess for a regional wall motion abnormality (WMA) consistent with the ECG finding could be considered. Patients with classic clinical presentation and ECG finding consistent with a STEMI who are COVID-19 possible should proceed to primary PCI. Ultrarapid COVID-19 testing (if available) helps determine the use of a dedicated CCL and postprocedural hospital unit placement. With any equivocal symptoms or ECG findings, a transthoracic echocardiogram, portable chest X-ray and serial ECGs should help determine the need for invasive coronary angiography. In consultation between the emergency department and interventional cardiology, consideration to coronary computed tomography (CT) angiography or CCL activation can then be made. *Primary PCI should always be performed with the universal use of personal protection equipment (PPE) for aerosolized and droplet precautions for the entire CCL team. COVID-19 = coronavirus 2019; CCL = cardiac catheterization laboratory; ECG = electrocardiogram; PCI = percutaneous coronary intervention; STEMI = ST-elevation myocardial infarction.

Mahmud E, Dauerman HL, Welt FGP, et al. *J Am Coll Cardiol* 2020;76:1375-84.

Procedural Characteristics

Left Main Artery Stenosis

Given the recommendations regarding a non-IRA, consideration should be made regarding the best revascularization strategy for an unprotected LM artery stenosis detected during an anterior STEMI. Significant LM disease, defined as ≥50% stenosis, is associated with increased morbidity and a five-year mortality rate of 57%, when not revascularized due to the large myocardial area at risk.[9]

Revascularization Trials of LM Disease

Three large randomized clinical trials have compared PCI to CABG for LM artery disease. The SYNTAX trial randomized 1,800 patients to PCI with first-generation TAXUS drug-eluting stents (DES) or CABG.[10] Patients were divided into three tertiles based on lesion complexity (SYNTAX scores 0-22, 23-32 and >32). The LM subgroup comprised 705 patients. For patients with complex disease (SYNTAX score >32), CABG was superior to PCI with lower rates of major adverse cardiovascular and cerebrovascular events (MACCE). The benefit was primarily driven by a significant decrease in repeat revascularization rates. In the other two tertiles, MACCE outcomes were similar for CABG and PCI.

NOBLE, a noninferiority trial, randomized 1,201 patients with LM disease (mean SYNTAX score 23) to either PCI with a biolimus-eluting stent (BioMatrix Flex) or CABG.[11] At the five-year follow-up, CABG performed better than PCI, with a significantly lower rate of MACCE (all-cause mortality, nonprocedural MI, repeat revascularization or stroke): 19% vs. 28% in the as-treated analysis. No difference was found between CABG and PCI, respectively, for all-cause mortality (9% vs. 12%; p=0.0040) and stroke (2% vs. 5%; p=0.073).

EXCEL, also a noninferiority trial, randomized 1,905 patients with LM stenosis (low or intermediate SYNTAX scores <32) to PCI with the second-generation everolimus (Xience) DES or CABG.[12] The landmark analysis for the period of 30 days to three years showed a significant difference for the primary endpoint in favor of CABG (7.9 vs. 11.5%; p=0.02). The primary outcome showed noninferiority (no between-group difference) for the composite of death from any cause, stroke or MI at three years (15.4% PCI vs. 14.7% CABG; hazard ratio [HR], 1.0; 95% confidence interval [CI], 0.79-1.26; p=0.98 for superiority). At five years, no significant difference was seen between PCI and CABG for the composite outcome of death, stroke or MI. The study investigators concluded the EXCEL trial data do not *a priori* support a preferential role for PCI over CABG in patients with LM disease and known prior cerebrovascular disease due to a higher rate of stroke seen in this patient subgroup.[13]

A meta-analysis of four clinical trials comparing PCI vs. CABG for LM stenosis (EXCEL, NOBLE, PRECOMBAT, SYNTAX) showed comparable outcomes for both revascularization strategies in patients with low-to-intermediate complexity, but more repeat revascularization after PCI (HR, 1.70; 95% CI, 1.42-2.05; p<0.001).[14] Another meta-analysis of five clinical trials (EXCEL, NOBLE, PRECOMBAT, SYNTAX, LEMANS) comparing PCI against CABG for LM stenosis showed no significant difference in the composite endpoint of death, stroke and MI (odds ratio [OR], 1.03, 95% CI, 0.80-1.4; p=0.70) and no difference in all-cause death (OR, 1.03; 95% CI, 0.81-1.32; p=0.81). However, a significantly higher rate of repeat revascularization was seen in the PCI group (OR, 1.76; 95% CI, 1.45-2.13; p<0.001).[15]

Guideline Recommendations For LM Revascularization

The ESC guideline recommends CABG for LM stenosis for all SYNTAX score groups (Class I, ESC 2018 guideline). However, PCI for LM stenosis is recommended for patients with a low SYNTAX score <22 (Class I, ESC 2018 guideline) and PCI for LM stenosis in patients with an intermediate SYNTAX score can be performed (Class IIa, ESC 2018 guideline).

Three documents recommend against PCI for LM stenosis in patients with a high SYNTAX score (≥33), including the ACC 2011 guideline,[16] the ACC/AHA 2016 appropriate use criteria for coronary revascularization in patients with acute coronary syndromes[17] and the 2018 ESC guideline (Class III). The 2011 ACC guideline recommends PCI for LM stenosis (Class IIa for low SYNTAX score and Class IIb for intermediate SYNTAX score).

Continued on next page

Procedural Considerations

- **DES are recommended.**

- **SYNTAX score should be calculated.** In the EXCEL trial, the STS risk score was shown to have poor discrimination for mortality (C statistic 0.507), but good discrimination for stroke (C statistic 0.751).[18] The predictive performance of the STS score for renal failure was good for CABG (C statistic 0.82), but poor for PCI (C statistic 0.59).

- **Outcomes differ by LM lesion location.** Ostial or LM shaft PCI is associated with lower risk for repeat revascularization vs. distal LM bifurcation.[19] At three years, EXCEL showed that ischemia-driven revascularization occurred more frequently after PCI than CABG in patients with LM distal bifurcation disease (13.0% vs. 7.2%; OR, 2.00; 95% CI, 1.41-2.85; p=0.0001), but was not significantly different in patients with disease only at the LM ostium or shaft (9.7% vs. 8.4%; OR, 1.18; 95% CI, 0.52-2.69; p=0.68) (p interaction, 0.25).[20] PCI for distal LM bifurcation disease is associated with worse long-term outcomes vs. CABG.[21]

- **PCI technique affects outcomes.** The DK crush technique, vs. provisional stenting for LM distal bifurcation lesions, at one year was associated with lower rates of target lesion failure (5% vs. 10.7%; p=0.02) and stent thrombosis (0.4% vs. 3.3%; p=0.02) in the randomized DKCRUSH-V trial.[22] Disease involving the ostial LCx should guide the choice of single-stent or double-stent technique, as it is not uncommon for the ostial Cx to become compromised after LM stent crossover from the proximal LAD to the LM.[23] The compromise in the ostial Cx occurs predominantly from carina shift.

- **IVUS helps.** Distal LM bifurcation PCI can be optimized by using IVUS to ensure optimal stent expansion at both the ostial LAD, ostial LCx and the distal LM.[24] Angiographic in-stent restenosis is predicted with IVUS-minimal stent area of 8.2 mm^2 for the proximal LM above the polygon of confluence, 7.2 mm^2 for the polygon of confluence, 6.3 mm^2 for the LAD artery ostium and 5.0 mm^2 for the LCx ostium. IVUS is useful for ostial LM stent positioning.

Figure 3 Strategic Categorization Of Coronary Interventions During COVID-19 Pandemic

Clinical condition	EMERGENT (do not postpone)	URGENT (perform within days)*	LOWER PRIORITY (perform within <3 months)*	ELECTIVE (may be postponed >3 months)
Ischaemic heart disease	• STEMI • NSTE-ACS in very high risk and high risk patients • Cardiogenic shock	• NSTE-ACS in intermediate risk patients • Unstable angina • Left main PCI • Last remaining vessel PCI • Decompensated ischaemic heart failure • Angina pectoris class IV • CABG in patients with NSTE-ACS unsuitable for PCI	• Advanced CAD with angina class III or NYHA III symptoms • Staged PCI of non-IRA in STEMI in patients with haemodynamic stability and without >90% lesions in proximal segments of major epicardial coronary arteries • Proximal LAD PCI	• CTO interventions • CCS with angina class II or NYHA II symptoms
Acute/chronic heart failure	• Mechanical circulatory support for cardiogenic shock (<65 years)	• Urgent heart transplant	• LVAD	

*Timing might be affected by overwhelming demand on resources in the setting of a COVID-19 pandemic.
CABG, coronary artery by-pass grafting; CCS, chronic coronary syndromes; CTO, chronic total occlusion; IRA, infarct related artery; LAD, left anterior descending; LVAD, left ventricle assist device; LVEF, left ventricular ejection fraction; NSTE-ACS, non-ST-segment elevation acute coronary syndrome; NYHA, New York Heart Association; PCI, percutaneous coronary intervention; STEMI, ST-segment elevation myocardial infarction.

Chieffo A, Stefanini GG, Price S, et al. *Eur Heart J* 2021;41:1839-51.

Case Wrap-Up

An IABP was inserted for hemodynamic support because the patient had SCAI Stage B shock. His SYNTAX score was 37. In keeping with our team-based care approach, we reviewed the patient's imaging with cardiovascular surgery and a joint decision was made to proceed with PCI. Using IV tirofiban bolus and infusion drip, we performed culprit-vessel revascularization, including treatment of LM disease, because of the volume of the myocardium at risk.

DES were deployed in the distal, mid and proximal LAD (2.5 x 38 mm, 3.0 x 32 mm, 3.0 x 24 mm, respectively). The ostial LM artery was treated with a 4.0 x 20 mm DES, which was postdilated with a 4.5 noncompliant balloon. Postprocedure angiography showed TIMI 3 flow in the distal vessel.

The patient was admitted to the intensive care unit. Transthoracic echocardiogram revealed a left ventricular ejection function of 24% with regional wall motion abnormalities and no hemodynamically significant valvular disease. DAPT with aspirin and clopidogrel was initiated, along with atorvastatin, lisinopril and spironolactone. The IABP was successfully removed after 24 hours and he was weaned off supplemental oxygen. Our infectious disease colleague recommended a five-day course of remdesivir and a 10-day course of dexamethasone for treatment of COVID-19 pneumonitis. Our patient was successfully discharged home on Day 6 to complete a two-week period of self-isolation for COVID-19 infection.

References available with the online version of this article at ACC.org/Cardiology.

Take-Home Points

- A Heart Team approach, with shared-decision-making with the patient, is recommended when considering revascularization options.
- Primary PCI is recommended for COVID-19 patients with STEMI.
- Culprit-only (IRA) revascularization is recommended for STEMI patients.
- Emergent surgical revascularization for COVID-19-positive STEMI patients with acute COVID pneumonitis/pneumonia is most likely not feasible at most health care centers.
- There is equipoise between percutaneous and surgical revascularization strategies for LM stenosis with low-to-intermediate SYNTAX score.
- Procedural management of ostial and mid shaft LM disease differs from distal LM disease.

QUESTION RECAP

What is your revascularization strategy?
It should be immediate PCI to the LAD and LM vessel.

Nkechi Ijioma, MD, FACC, is senior associate consultant cardiologist with the Mayo Clinic Health System in La Crosse, WI. She acknowledges and appreciates the expert content review by **Jose Emilio Exaire, MD, FACC**, at Mayo Clinic; **Kwan S. Lee, MD, FACC**, at the University of Arizona, Tucson; and **S. Michael Gharacholou, MD**, at Mayo Clinic.

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St. Luke's University Health Network
Christine.Figler@sluhn.org

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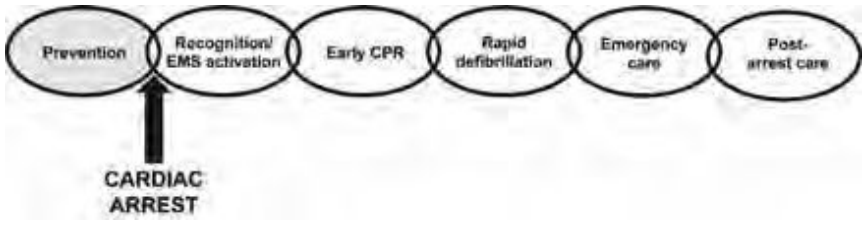
A Paradigm Shift in the Management of **Outside Hospital Cardiac Arrest**

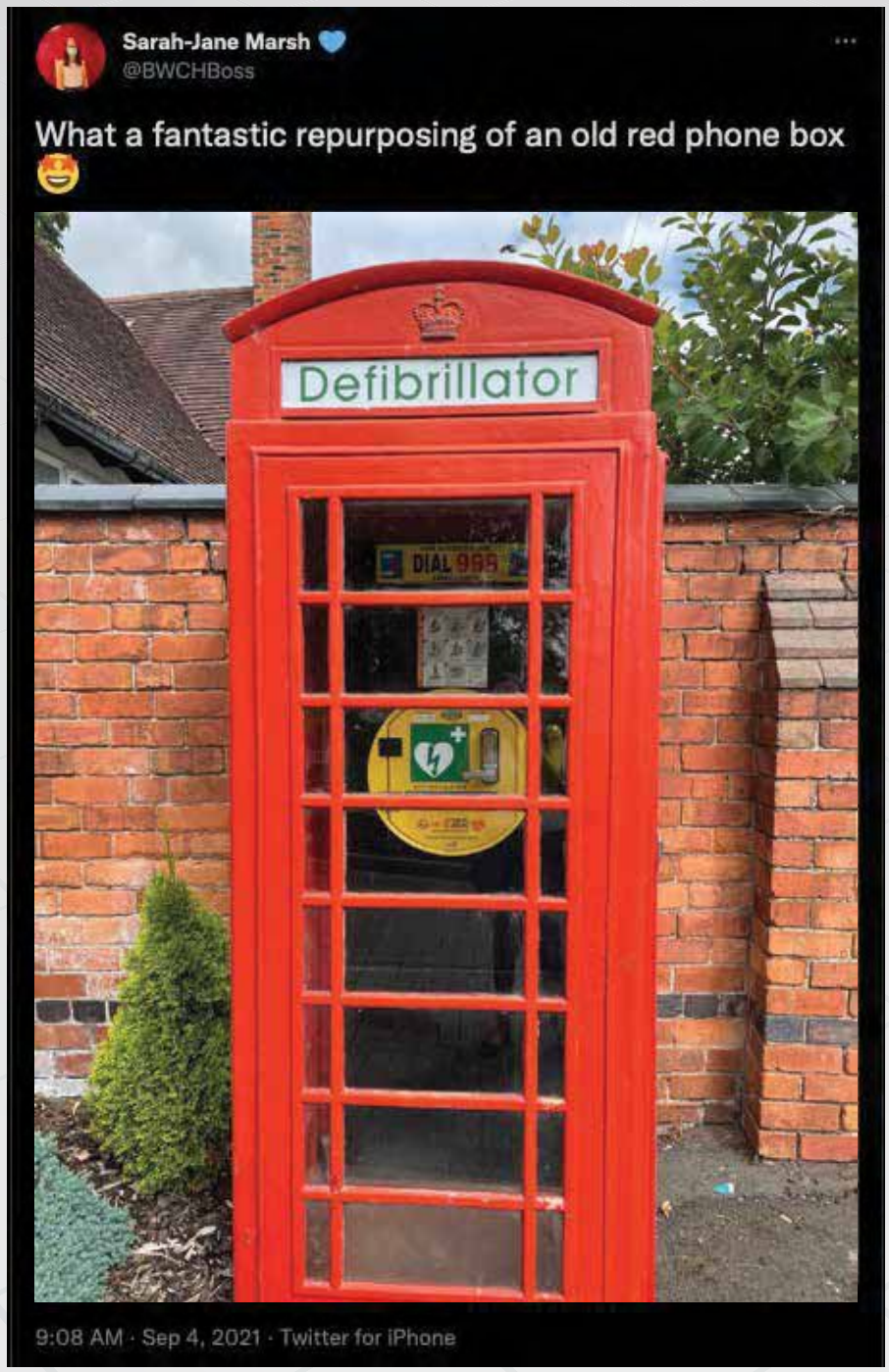
Every year more than a half million cardiac arrests occur in the U.S., and more than half of these events occur outside the hospital setting. Management of outside hospital cardiac arrests (OHCA) is critically dependent on initiating CPR and providing external defibrillation in a timely manner. Despite numerous attempts to improve emergency response systems, including the strategic deployment of AEDs in public places, OHCA outcomes have remained dismal with survival to hospital discharge rates of 10-12%.[1]

More recent efforts to optimize the chain of survival in OHCA have focused on engaging community activists who are able to provide basic life support in a more timely manner until emergency medical services (EMS) are available **(Figure 1)**. During the COVID-19 pandemic, however, the stay-at-home mandates, calls for social distancing and public fear of disease transmission may have dissuaded community responders from assisting in OHCA.

Figure 1 Chain of Survival in the Management of OHCA



Mitrani, RD. et al. J Am Coll Cardiol EP 2021; 7:12-15.



An investigation of OHCA outcomes during the COVID-19 pandemic confirmed this suspicion and revealed its detrimental impact on OHCA survival rates. Uy-Evanado, et al., compared consecutive cases of prepandemic OHCA cases (March to May 2019) with consecutive canvases of pandemic OHCA cases (March to May 2020) in two communities from Oregon and California.[2] From the prepandemic to the pandemic period, the number of OHCA cases increased by nearly 25% **(Figure 2)**. Compared to the prepandemic period, during the pandemic period there was a significant increase in the proportion of OHCA cases occurring in the home (76% vs. 73%; p=0.009), a significant increase in EMS response time (7.6 mins vs. 6.6 min; p<0.001) and a significant decrease in the proportion of OHCA cases involving bystander CPR (51% vs. 61%; p=0.002) and bystander use of AEDs (1% vs. 5%; p=0.002). Overall, OHCA survival to hospital discharge during the pandemic period was nearly 50% lower than during the prepandemic period (7.9% vs. 14.7%; p=0.02).

More recent efforts to improve survival rates in OHCA have focused on utilizing technology to facilitate response times. Andelius, et al., evaluated the use of a smartphone-based activation of community responders in OHCA cases and its impact on bystander CPR and AED use in the capital region of Denmark from 2017-2018.[3] Community responders were adult volunteers who were not required to have CPR and/or AED training. However, nearly 99% of volunteers had received CPR training and 26% were health care professionals. At the time of a suspected OHCA, a centralized emergency dispatch system would reach out to nearby com-

munity responders and coordinate efforts to localize the OHCA location, start CPR, and/or retrieve a nearby AED. After the event had resolved, responders were surveyed on whether physical injury or psychological distress was experienced.

Of the 6,836 responders who were alerted in 438 OHCA cases, 51% (n=3,480) responded to the alarm, and 47% (n=1,623) accepted the alarm. In 8% of OHCA cases no responders accepted the alarm. In 42% of OHCA cases, community responders arrived before EMS and this was associated with a significantly higher percentage of bystander CPR (85.3% vs. 76.8%; p=0.027) and AED use (21.2% vs. 6.7%; p<0.001). The longer it took for EMS to arrive at an OHCA, the more likely it was for a community responder to be the first to arrive: community responders arrived before EMS in 23.3% of cases when EMS response time was <5 minutes and in 71.2% of cases when EMS response was >10 minutes **(Figure 3)**. There was a trend towards improved 30-day survival in OHCA cases when citizen responders arrived before EMS (16.1% vs. 13.1%; p=0.38).

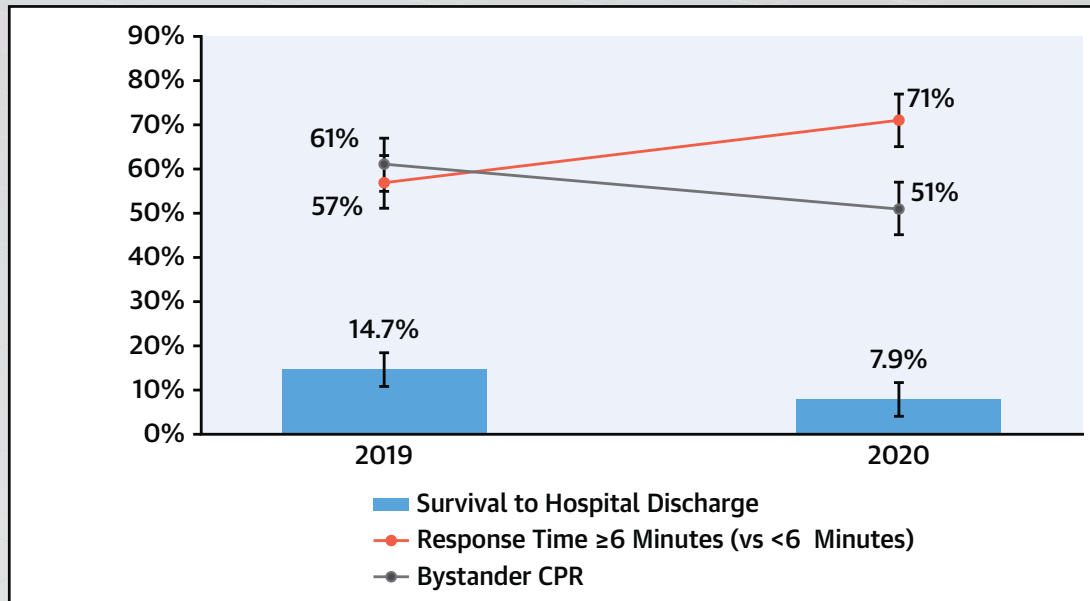
A separate study by Schiebeck, et al., assessed the feasibility of using drones (unmanned aerial vehicles) to deliver AEDs to locations of suspected OHCA to assist standard EMS response in a semi-urban region of Sweden in 2020.[4] Drones were available for dispatch between 8 a.m. and 10 p.m. (during regulated air space time) but their use was limited by inclement weather (darkness, rain and wind ≥8 m/s) and geographic constraints (no-fly zones, buildings ≥5 stories, and outside of administrative range).

Of the 53 alerts of suspected OHCA during the study period, 74% were prohibitive for drone use. In the 14 cases eligible for drone use, a drone was dispatched in 12 cases (86%) and successfully delivered an AED in 11 cases (92%). The median distance traveled by the drone (hanger to suspected OHCA location) was 1.9 miles and there was 100% accuracy in delivering the AED within 10 feet of the expected drop off point. In seven of these cases (64%), the drone arrived prior to EMS with a median time benefit of 1:52 minutes. Of note, the delivered AED was not attached to the patient until EMS arrived.

While the results from these two studies are promising, it is unclear whether similar positive outcomes could be expected from the use of these technologies in less urban areas, where smartphone and drone utilization may be less prevalent. It is also unknown whether communities will embrace having untrained bystanders or unmanned vehicles involved in emergency care. Furthermore, additional concerns related to patient privacy and data security will need to be addressed before these consumer technologies can be adopted in the health care setting. Nonetheless, these proof-of-concept studies highlight exciting innovations that may improve survival in OHCA.

As the COVID-19 pandemic continues to strain the availability of medical resources and health care providers, community responders will be increasingly relied upon to expedite resuscitation efforts in OHCA. Effective incorporation of bystanders into the chain of survival for OHCA, however, will require significant updates to the current emergency response system. At the very least, community responders should be provided appropriate personal protective equipment and testing for COVID-19 to reduce infection transmission concerns. Perhaps community responders for medical emergencies should also be offered incentives for their availability, similar with airplane passengers who are assigned larger exit row seats to assist with potential flight emergencies. Whatever the solution to this dilemma may be, it will undoubtedly utilize novel technologies to educate, engage and empower community responders to play a greater role in the management of OHCA.

Figure 2 Impact of Covid-19 Pandemic on OHCA



Uy-Evanado, A. et al. J Am Coll Cardiol EP. 2021;7(1):6–11.

Figure 3 Impact of Citizen Responders on OHCA

Andelius, L. et al. J Am Coll Cardiol. 2020;76(1):43–53.

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This article was authored by **Edward Chu, MD**, (@Ed_Chu_MD), an electrophysiology attending physician in Miami. He just completed his fellowship training at Mount Sinai Medical Center in New York.

Wellness For Cardiovascular Trainees **in the Era of COVID-19**

Our world changed in March 2020. The first cases of COVID-19 were identified in the U.S. and the idea of front-line health care workers took on a deeper meaning. At that time, our understanding of what the virus could do, how it could be transmitted and how it could be treated was unclear at best. We wondered if we would have enough personal protective equipment (PPE) to safely care for patients. This progressed to the understanding that we may not have enough beds, ventilators or even health care workers.

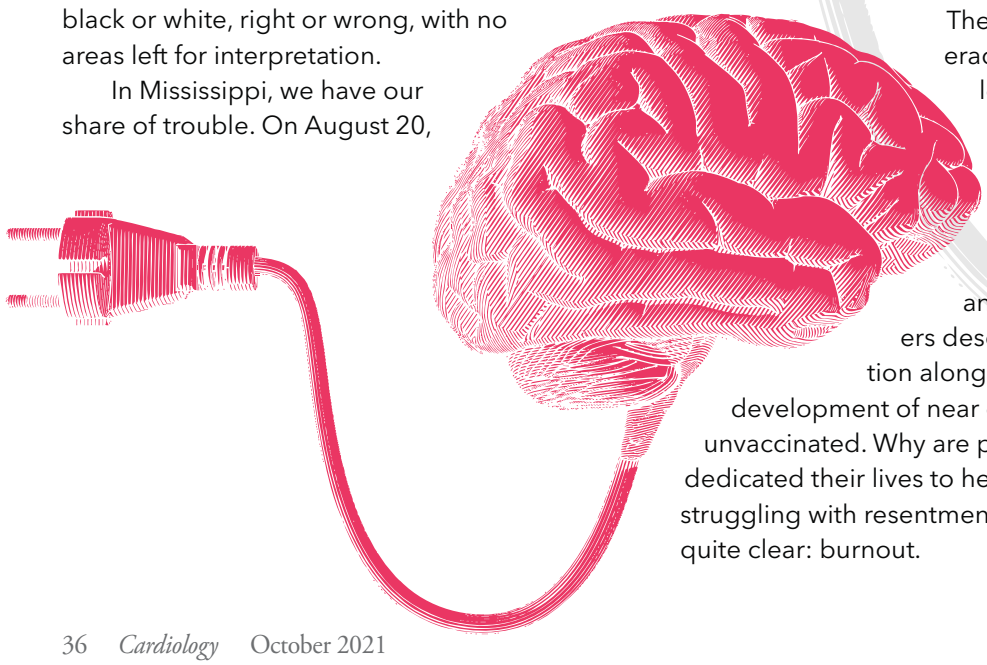
Fellowship programs thought about how to best ration their fellows to maintain an uninterrupted service line and training environment. Clinic rotations turned virtual and meetings moved online. Adapting to this new way of life was uncomfortable, and honestly frightening, because none of us had ever managed a pandemic like this.

The evolution of thought and emotion can be seen on social media. Through the pandemic, I have been scrolling through personal social media accounts and news articles to stay abreast of the latest developments. This routine is where I gather frustration, amusement and information, but I'm often disheartened. In the beginning, there was general concern from the public and a certain respect for what the authorities were doing. Soon, frustration with social distancing emerged. I began to see debates rage over the steps to prevent COVID-19 with mask effectiveness and school attendance policies as headlining topics. When actual treatments came online, the debates combined with politics and turned to the utility of different therapeutics. Now we're still debating past topics and vaccination has been added to the mix. All of these are on display with assumptions that every side is black or white, right or wrong, with no areas left for interpretation.

In Mississippi, we have our share of trouble. On August 20, a story in the *Mississippi Free Press* plus a tweet from @EricTopol let me know that my home and current state was leading the entire world in COVID-19 cases.[1,2] The author William Faulkner said, "To understand the world, you must first understand a place like Mississippi." I have a lot of pride in the people of my state for many reasons. The people's industriousness, friendliness and jovial spirit that resonate in our music and art are topping this list.

However, scrolling as I do, you'd think we are at war with one another. Our clinics and hospitals are overrun, with the Mississippi State Department of Health reporting case numbers higher than we have ever seen.[3] My own institution now hosts both federal forces and the charitable organization Samaritan's Purse, which set up field hospitals in two of our parking garages. A year and a half into the pandemic, even with an effective vaccine, there are so many patients that we're putting people outside, in one of my old parking spaces, in deep south Mississippi in August because this is the only place left.

We physicians want to help make the situation better. In the beginning, we encouraged our patients to stay home, social distance and mask up. We felt that we just had to get to the point of vaccination to end the pandemic. Now, vaccines are widely available. But much like many of you, I am meeting resistance when discussing vaccination with my patients. There are concerns over myocarditis, fertility, the makeup of the vaccine, and the list continues. Many of these concerns are reflected in social media and driven by misinformation. I do my best to dispel myths, encourage prevention measures and, of course, vaccinate, but there are still many who decline.



The road to COVID-19 eradication has been long, and it seems the finish line keeps being moved back with no real end in sight. With this, I find more and more physicians and health care workers describing their exhaustion along with the unexpected development of near contempt towards the unvaccinated. Why are people who have dedicated their lives to helping others now struggling with resentment? I think the answer is quite clear: burnout.

Understanding Burnout

In 1996, The Maslach Burnout Inventory Manual described burnout as "a psychological syndrome of emotional exhaustion, depersonalization, and reduced personal accomplishment that can occur among individuals who work with other people."[4] The manual goes on to describe emotional exhaustion as "that which makes workers feel they have nothing left to give at a psychological level."

The depersonalization is described as "negative, cynical attitudes and feelings about one's clients," which "can lead staff members to view clients as somehow deserving of their troubles." This problem was not only for mid- to late-career physicians but also for trainees. A 2009 burnout literature review published in *The Journal of Graduate Medical Education* yielded an estimate that, depending on specialty, 27-75% of residents experienced burnout.[5]

> "For myself, putting patient care at the front of my mind helps me stay in an affable and effective mindset. **When I consider the needs of the patient first, even late at night,** I feel a connection to my work and a sense of well-being follows."

For myself, this pandemic most certainly brought emotional exhaustion. At points, daily schedule changes became essentially expected. Concern over not only catching the virus but bringing it home to my family was constant. Social distancing strained personal relationships. Obtaining and wearing full PPE to see patients with suspected or confirmed COVID-19 added valuable time and complexity to what might have otherwise been straightforward consults. Topping this complexity with the further development of distrust and vaccine hesitancy, as the pandemic drags on, makes it no surprise that depersonalization has begun.

Given all this, it's no wonder that fellows may now lack a sense of personal accomplishment. An article published in the *Journal of the American College of Cardiology (JACC)* detailed the results of an April 2020 survey distributed to adult and pediatric

cardiology FITs.[6] Just over 28% of cardiology fellows responded. Of these, 41% were uncomfortable with institutional PPE recommendations, 81% were anxious about contracting COVID-19, and 69% reported that their call schedule was changed by the pandemic. The majority of respondents had concerns over their ability to meet educational requirements and their future job opportunities.

ACC's 2020 Well-Being Study of 1,288 cardiologists, fellows in training (FITs) and cardiovascular team members conducted in November 2020 found that burnout nearly doubled when comparing pre- to peak COVID-19 levels, reaching 38%.

Though these perceived pressures evolved through the pandemic, burnout as a problem among cardiovascular professionals and trainees precedes the pandemic. Results of the 2016 ACC Professional Life Survey showed that 27% of U.S. cardiologists are burned out, and nearly 50% reported being stressed with less energy.[7]

Taking Action

The ACC has made addressing clinician wellness a Strategic Priority. The Board of Governors (BOG) Task Force on Member Wellness combined efforts with the Membership Work Group on Wellness in spring 2019 to increase awareness and sense of wellness, work on strategies to mitigate burnout and engage clinicians along the way.

Scan the QR code for a *JACC* Leadership Page from the BOG Task Force on the imperative of addressing clinician well-being.

Among the tangible outcomes from this work is the Clinician Well-Being Portal, with links to ACC advocacy efforts to reduce administrative burdens, detailed well-being resources and events, as well as information centering around diversity and inclusion. The wellness initiatives across all ACC committees are cataloged by the membership wellness work group. The portal also includes a link to the official ACC Member Hub Well-Being and Burnout group, where members are encouraged to connect and discover outlets for improving their lives. Finally, the site has been updated with an entire section on COVID-19-specific well-being news, articles, podcasts and other resources.

Visit the Clinician Well-Being Portal at *ACC.org/ClinicianWellBeing*. Scan the QR code for the COVID-19 wellness resource.

For FITs specifically, the BOG Task Force made recommendations and provided access to resources included on the Well-Being Portal. The FIT/Early Career Webinar Series provides on-demand webinars on wellness, burnout and work-life balance.

Scan the QR code for the complete list and start viewing.

One of these on-demand webinars has resonated with me. **Morton J. Kern, MD, FACC**, discusses specific habits that will lead FITs to successful and balanced careers. He encourages fellows to be available, affable, effective and dependable. For myself, putting patient care at the front of my mind helps me stay in an affable and effective mindset. When I consider the needs of the patient first, even late at night, I feel a connection to my work and a sense of well-being follows. Kern also talks about how prioritization becomes important as we are pulled in many different directions. Often this means prioritizing time and tasks not only at work, but at home too. I am married with two little boys and can say without a doubt that the best part of my day is spending time with family. At home, I try to stay undistracted and in the loop about their lives.

Time at home allows me to recharge and more readily reconnect with my patients and coworkers when I get back to work. Balancing home and work life is not easy. It requires that we identify what recharges us, recognize the limits to our time and attention, and be realistic when it comes to accepting extracurricular assignments.

Six systemic changes as the focus of wellness efforts were defined by the BOG Task Force in its Leadership Page.[8] In relation to our institutions and fellowship programs, I think there are several areas on which to focus. Keeping a positive work and educational environment is key. We can accomplish this with social events outside of the hospital, inquisitive and nonjudgmental learning environments, and allowing space for fellows to cover for one another when "life happens." Additionally, I think the transition from residency to fellowship is a prime opportunity to welcome fellows into their new environment and focus on streamlining the transition through effective and efficient orientation.

During fellowship, we are forming the habits that will make up our daily practice. Now it becomes critical that we develop the skills to identify when we, or those around us, are struggling. We must begin using the resources available at our institutions and at the ACC level to mitigate burnout and promote wellness. The table shares actions we can take at the individual, institutional, organizational and societal level to combat burnout.

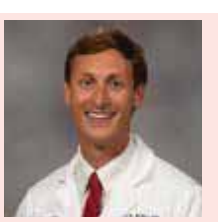
When the ACC Board of Trustees included the initiative to improve clinician well-being in the 2020-2023 Strategic Plan, I doubt anyone could have predicted just what a challenge COVID-19 would present. In July of this year, the ACC, American Heart Association, European Society of Cardiology, and World Heart Federation issued a joint statement calling for global action to improve clinician well-being.[9] Specifically, they urged health care organizations to support their employees' psychosocial health, create an infrastructure where they can thrive, and give a space for reporting of mistreatment with emphasis on normalizing access to mental health resources. For medical societies, they asked for continued input on wellness and health policy change advocacy to health care organizations, creation of access to efficiency and knowledge toolkits, and focus on diversity, equity and inclusion.

As fellows, we are undoubtedly the future of cardiology. Training through the pandemic has left us changed, to be certain, but resilient as well. It is up to us to prioritize well-being for ourselves and our future patients and practices.

References available with the online version of this article at ACC.org/Cardiology.

Table Actions to Promote Wellness

INDIVIDUAL LEVEL
Spend 20% of time at work on things meaningful to you
Connect with colleagues
Strive to be affable and available
Prioritize tasks
Find outside activities that recharge you
Seek help when needed
INSTITUTIONAL LEVEL
Create a work environment centered on clinician wellness
Support psychosocial health
Commit to diversity, equity and inclusion
Encourage a positive fellowship learning environment
Reduce administrative burden
Commit to digital transformation
Allow for a mistreatment reporting system
ORGANIZATIONAL LEVEL
Advocate for wellness and health policy change
Commit to diversity, equity and inclusion
Create access to efficiency and knowledge toolkits
Promote use of ACC Well-Being Portal
Promote use of ACC Member Hub Well-Being and Burnout Group
Promote use of ACC Webinars
SOCIETAL LEVEL
Promote wellness research



This article was authored by **Andrew D. Brown, MD**, a fellow in training in the Division of Cardiovascular Diseases at the University of Mississippi Medical Center in Jackson, MS.

Time For Action: Tell Congress to Protect Patient Access to Medicare Services

On Jan. 1, 2022, physician practices face an array of significant reductions in Medicare payments due to a series of statutory and regulatory cuts. These looming cuts would have devastating impacts on cardiology practices working on the front lines treating Medicare patients, many of whom are at greatest risk for COVID-19.

"Individually, each of the reductions would be painful; taken together, they would be devastating," said ACC President **Dipti Itchhaporia, MD, FACC,** during ACC's 2021 Legislative Conference. "We must ask members of Congress to act now to stop the cuts and ensure Medicare patients have access to cardiovascular services."

Among the anticipated cuts:

- Expiration of the current reprieve from the 2% Medicare sequester created by the Budget Control Act of 2011, which now is expected to continue into 2031, despite being originally slated for sunset in 2021.
- Imposition of a 4% Statutory PAYGO sequester resulting from passage of the American Rescue Plan Act of 2021.
- Expiration of the congressionally enacted 3.75% temporary, public health emergency-linked increase in the Medicare physician fee schedule (PFS) conversion factor to avoid payment cuts associated with budget neutrality adjustments resulting from Medicare policy changes.
- Substantial reduction of roughly 25% for electrophysiology ablation services resulting from updated physician work values included in the proposed 2022 Medicare PFS.
- Practice expense decreases ranging from 5% to 20% for services such as echocardiography, advanced imaging and office-based vein therapies resulting from a necessary adjustment to clinical labor rates included in the proposed 2022 PFS.

The ACC is actively engaged in communicating with Congress to convey how detrimental these cuts will be to patient care and the topic was top-of-mind during hundreds of virtual meetings with congressional leaders and their staff as part of the Legislative Conference this month. ACC members are encouraged to help amplify these messages by contacting their members of Congress and urging support to stop the cuts.

Scan the QR code to learn more and take action.

For more information about other health policy issues discussed with lawmakers as part of the 2021 Legislative Conference, visit *ACC.org/LegislativeConference*.

More **COVID-19 Relief** Funding On the Way

The U.S. Department of Health and Human Services (HHS), through the Health Resources and Services Administration (HRSA), has released $25.5 billion in funding for health care providers affected by the COVID-19 pandemic. The funding includes $8.5 billion in American Rescue Plan resources for providers who serve rural Medicaid, Children's Health Insurance Program (CHIP) or Medicare beneficiaries, as well as $17 billion in Provider Relief Fund (PRF) Phase 4 payments for providers who can document revenue loss and expenses related to the pandemic.

PRF Phase 4 payments will reimburse smaller providers, who often serve vulnerable and isolated communities, for lost revenue and COVID-19 expenses at a higher rate compared with larger providers. In addition, PRF Phase 4 payments will include bonus payments for providers who serve Medicaid, CHIP and/or Medicare beneficiaries. Similarly, HRSA will make American Rescue Plan rural payments to providers based on the amount of Medicaid, CHIP and/or Medicare services they provide to patients who live in rural areas. Providers will be able to apply for both programs in a single application, and HRSA will use existing claims data to calculate payments.

Additionally, HHS has delayed the final 60-day grace period for providers who failed to meet the Sept. 30 PRF reporting requirement deadline.

Scan the QR code for information about eligibility requirements, application requirements and the application process for PRF Phase 4 payments and American Rescue Plan rural payments.

ACC Comments on **CMS 2022 Medicare PFS** Proposed Rule

In a formal comment letter to the Centers for Medicare and Medicaid Services (CMS) on the proposed 2022 Medicare Physician Fee Schedule (PFS), the ACC addresses payment policy and technical changes that drive payment for individual services, as well as other programmatic topics related to the Quality Payment Program, Merit-Based Incentive Payment System (MIPS) Value Pathways (MVPs) and others outlined for 2022.

As part of the comments, the ACC urges CMS not to finalize a broad proposal that would require billing of split/shared visits by physicians and advanced practice providers exclusively by time. Additionally, the letter urges the Agency not to finalize a proposal that would increase practice expense costs for clinical staff labor in a manner that precipitously reduces payment for other services. Proposed work relative value unit (RVU) reductions that result from bundling several services involved in electrophysiology ablation are also addressed in detail, with the ACC urging caution, accuracy and a phase-in of any significant reductions that may still occur.

CMS is expected to release the final 2022 Medicare PFS, as well as the 2022 Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payments rule, in early November. Scan the QR code to read the full PFS comment letter.

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Jumping For Joy: Finding Clinician Wellness During the Pandemic

Looking back at the last 18 months, I'm reminded of the difficulty and privilege of caring for patients. Like many of my colleagues, I grapple with balancing the emotional and physical need to keep my patients healthy and the demands placed on me by the imperfect models of care delivery.

Unfortunately, there are times when these forces collide, and we're caught in the middle. As a physician, I've always felt this means to care for my patients as if they are my very good friends. This belief has led me to become friends with many of my patients.

I can happily say my friendship with Chuck has taken me to new heights! We met when he was around the young age of 90, when he had a heart attack after a knee replacement. This was also when he started skydiving.

Chuck served in the U.S. Navy during World War II. Every year he looked forward to celebrating his birthday with a jump and every year he would ask me to go. Through a heart attack, valve replacement and arrhythmia, he just kept going. He even teaches as a senior exercise instructor at his retirement community!

Finally, for his 95th birthday, I agreed to jump with him. We had a fantastic time. The feeling was immensely exciting, yet peaceful. Sharing it with my friend made it very rewarding.

Our jump celebrated his determination and spirit and my love for the people I serve. Chuck is a great lesson for all of us. In all things, keep moving, find your passion – and enjoy it with your friends!

Share the Memories

Patients are at the heart of all we do. Share photos of your most memorable moments with a patient on Twitter using **#CardiologyMag** and tagging **@ACCinTouch.**

This article was authored by **Nicole L. Lohr, MD, PhD, FACC,** governor of ACC's Wisconsin Chapter and associate professor of medicine in the Cardiovascular Medicine Division, Medical College of Wisconsin, in Milwaukee.

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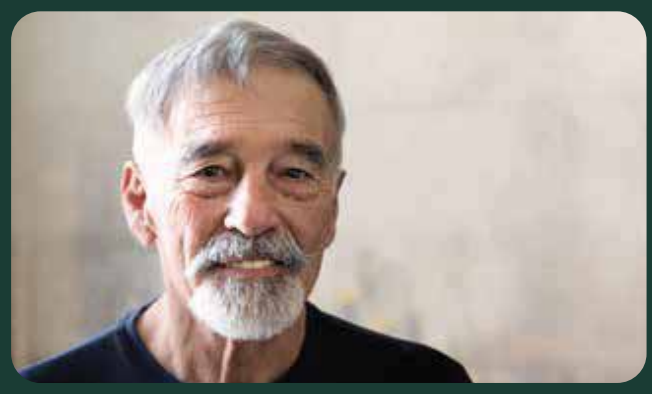
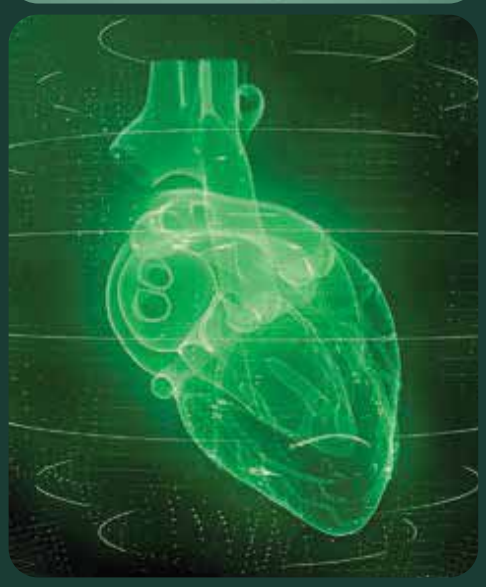
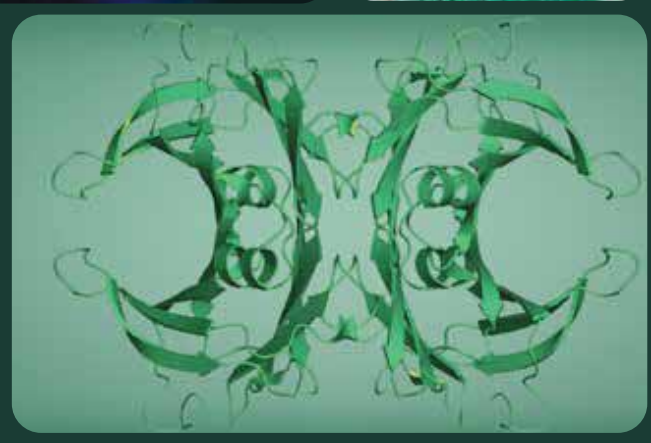
ATTR-CM is caused by destabilization of the transthyretin (TTR) protein[1]



Destabilized TTR can result in a high-burden systemic disease[2]



TTR is an evolutionarily conserved protein with important functions in the body[3]



Lower levels of TTR are associated with poorer health outcomes[4,5]

Are your patients suffering from transthyretin amyloid cardiomyopathy (ATTR-CM)?

TTR is a naturally occurring, relatively abundant protein responsible for transporting thyroxine and retinol throughout the body.[6] Unstable TTR tetramers dissociate into monomers, which can aggregate into amyloid deposits in the heart muscle—a path that can ultimately lead to heart failure.[2] ATTR-CM is an underrecognized and underdiagnosed disease with high unmet need.[7] If untreated, median survival has been shown to be less than 2 years.[8]

When it comes to ATTR-CM, what you may not know matters.

Stay in the know at TTRmatters.com.

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